IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

BALTIMORE CITY BOARD OF SCHOOL COMMISSIONERS, on behalf of itself and all others similarly situated, Plaintiff, v. ELI LILLY AND COMPANY; NOVO NORDISK INC.; SANOFI-AVENTIS U.S. LLC; EVERNORTH HEALTH, INC. (FORMERLY EXPRESS SCRIPTS HOLDING COMPANY); EXPRESS SCRIPTS, INC.; EXPRESS SCRIPTS ADMINISTRATORS, LLC; MEDCO HEALTH SOLUTIONS, INC.; ESI MAIL PHARMACY SERVICES, INC.; EXPRESS SCRIPTS PHARMACY, INC.; ASCENT HEALTH SERVICES L.L.C.; CVS HEALTH CORPORATION; CVS PHARMACY, INC.; CAREMARK RX, LLC; CAREMARK PCS HEALTH, LLC; CAREMARK, LLC; ZINC HEALTH VENTURES, L.L.C., ZINC HEALTH SERVICES, L.L.C., UNITEDHEALTH GROUP, INC.; OPTUM, INC.; OPTUMRX INC.; OPTUMINSIGHT, INC., EMISAR PHARMA SERVICES L.L.C., Defendants.	Case No. 1:25-cv-00096 **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

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On behalf of itself and all others similarly situated school systems, Plaintiff BALTIMORE CITY BOARD OF SCHOOL COMMISSIONERS, which operates a system of public schools in Baltimore City commonly known as the Baltimore City Public School System or Baltimore City Public Schools ("City Schools"), brings this action against the above-named Defendants, alleging as follows:

I. INTRODUCTION

1. The price and availability of diabetes medications in this country are substantially controlled by two groups of actors, drug manufacturers and behemoth conglomerates usually called "pharmacy benefit managers" ("PBMs"). The PBMs are middlemen charged with overseeing prescription drug pricing, dispensing, and reimbursement for more than 200 million Americans and with reducing healthcare costs for health plan sponsors, but often they do the opposite. Together, the drug manufacturers and PBMs have conspired and are engaged in an ongoing conspiracy to rig the market for prescription diabetes medications through a pattern of unfair and deceptive trade practices and racketeering activity, as part of which:

(a) The drug manufacturers pay the PBMs illegal kickbacks, disguised as "rebates";

(b) In return, the PBMs protect the drug manufacturers from competition and abdicate (but still tout) their role to generate savings for health plan sponsors (and patients). They actually collude with the drug manufacturers to raise rather than lower prescription drug prices, with diabetes medications as the poster child for their scheme;

(c) When choices are available between equivalent low-priced and high-priced drugs of the same therapeutic class, the drug manufacturers and PBMs often conspire to systematically exclude the lower-cost option from health plan formularies, foreclosing access under most prescription drug benefit plans;

(d) The drug manufacturers and PBMs take active steps to thwart and prevent any possibility of market self-correction by affirmatively concealing and misrepresenting what they are doing, for example, by calling kickbacks "rebates," then further disguising the same payments as "fees," by using gag clauses and offshore affiliates and limiting plan sponsors' audit rights to add additional layers of secrecy, and by making their schemes to overcharge health plan sponsors (and patients) so pervasively complicated and opaque as to make it almost

impossible for health plan sponsors (or patients) to understand.

2. Diabetes medications are the poster child for the drug manufacturers and PBMs' drug pricing scheme (the "Insulin Pricing Scheme"). As a result of their collusion in the prescription drug market, while the average cost of consumer goods and services has risen 1.75-fold over the past twenty years, the cost of some diabetes medications (the "at-issue drugs") has risen more than tenfold. And the reason is Defendants' Insulin Pricing Scheme, which is the subject of this complaint.

3. In recent years, one in four healthcare dollars has been spent in this country caring for people with diabetes. Much of that money is spent by employers like school districts, self-funding prescription drug plans for their employees and their dependents. Defendants' Insulin Pricing Scheme has cost Plaintiff City Schools—and other schools districts across the country that self-fund their prescription drug plans—to overpay for the at-issue drugs.[1]

4. Across the country, there are several thousand school districts with self-funded plans. They are the members of the proposed Class. The drug manufacturers and PBMs' Rigged Pricing Scheme has cost many of them millions of dollars.

5. Diabetes medications—mostly, insulins—have been manufactured for sale in the United States since 1922. For most of that time, they were affordable. As recently as 1999, the average list price of Humalog, a widely used insulin produced by Defendant Eli Lily, was $21 a vial. But over the last dozen or so years—because of Defendants' Insulin Pricing Scheme—the pricing has changed dramatically. By 2017, the price of Humalog, which sold for $21 in 1999, had soared to more than $274—a staggering increase of more than 1,200%.

[1] The Manufacturer Defendants' at-issue diabetes medications (the "at-issue" drugs) are listed in paragraph 104 Figure 3.

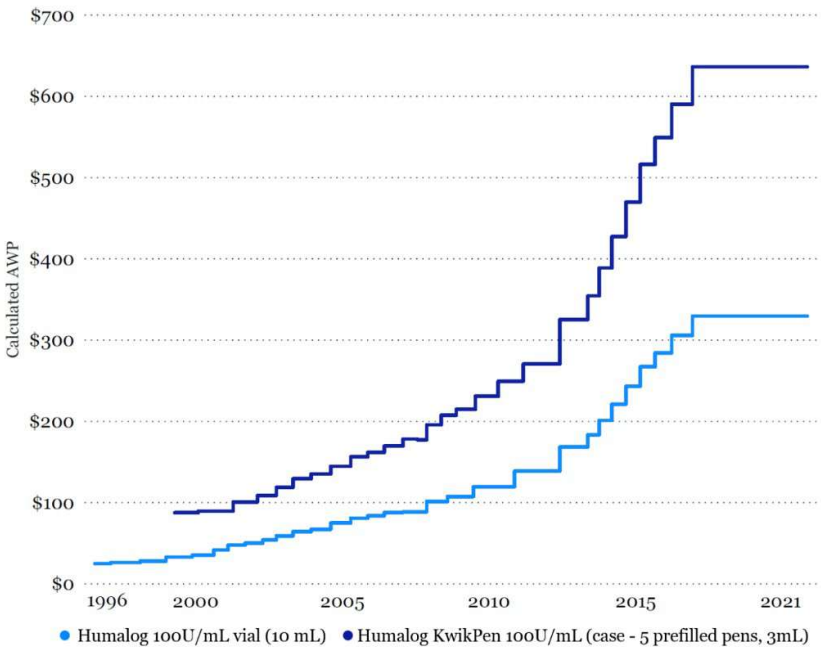
6. That $274 vial of synthetic insulin is essentially the same product the Manufacturers sold for $20 in the 1990s. The difference is not the quality of the product or the cost of producing it, which, in fact, has *decreased.* It is Defendants' Insulin Pricing Scheme.

7. As Kasia Lipska, an endocrinologist at the Yale School of Medicine and Clinical Investigator at the Yale-New Haven Hospital Center for Outcomes Research and Evaluation, has explained:

> We're not even talking about rising prices for better products here. I want to make it clear that we're talking about rising prices for the same product . . . . [T]here's nothing that's changed about Humalog. It's the same insulin that's just gone up in price and now costs ten times more.[2]

8. As a result of the Manufacturer Defendant and PBM Defendants' Rigged Price Scheme, the price hikes for diabetes medications have been staggering. Figure 1 shows how Defendant Eli Lilly raised the list price of its insulin product Humalog from 2006-2021.

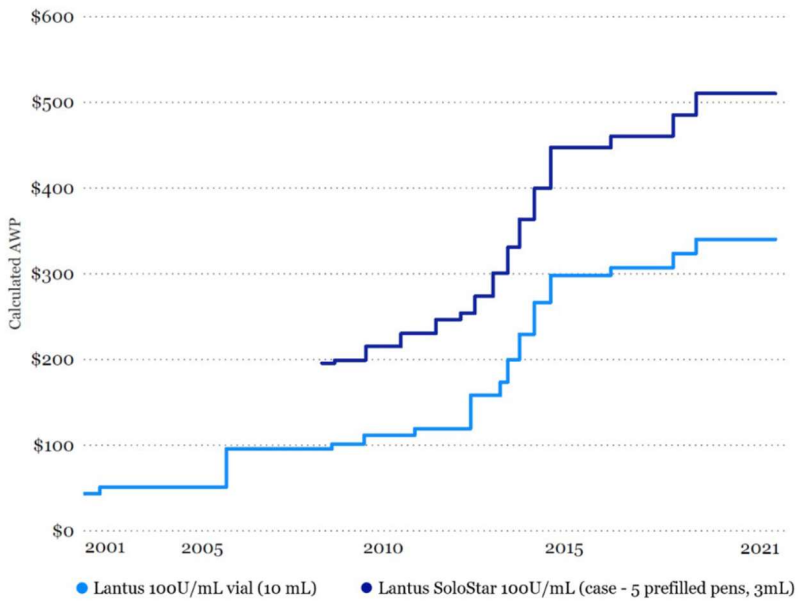
Figure 1: Rising List Price of Eli Lilly's Levemir, 1966-2021



[2] Natalie Shure, *The Insulin Racket,* AMERICAN PROSPECT (June 24, 2019), https://prospect.org/health/insulin-racket/ (last visited Apr. 24, 2024).

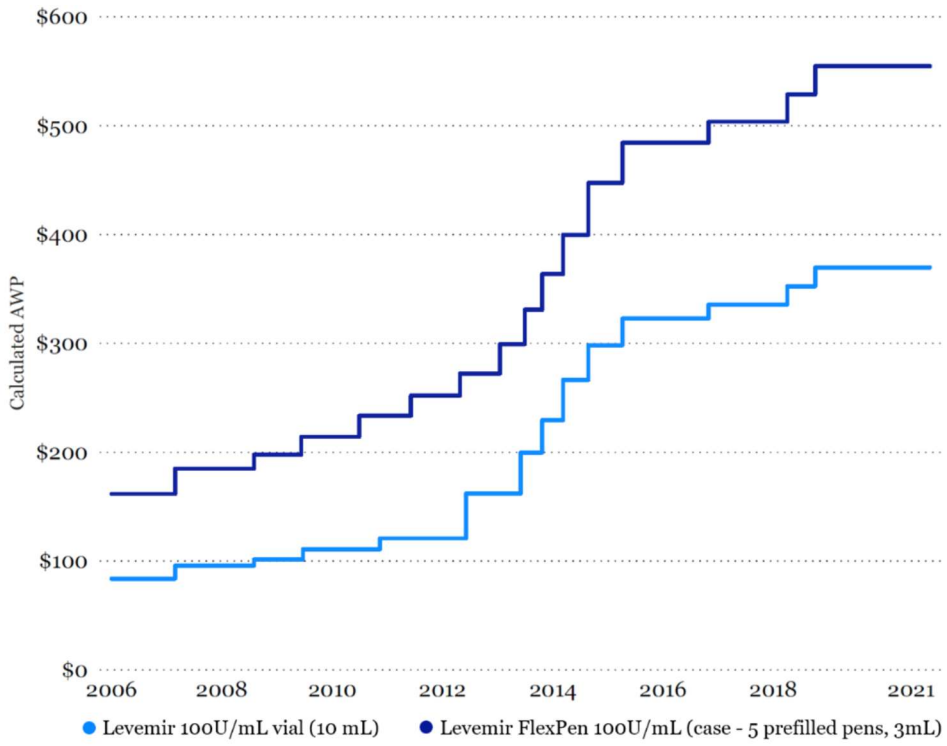
9. Figure 2 shows how Defendant Sanofi raised the price of its insulin product Lantus from 2006-2021.

Figure 2: Rising List Prices of Sanofi's Lantus, 2001-2021



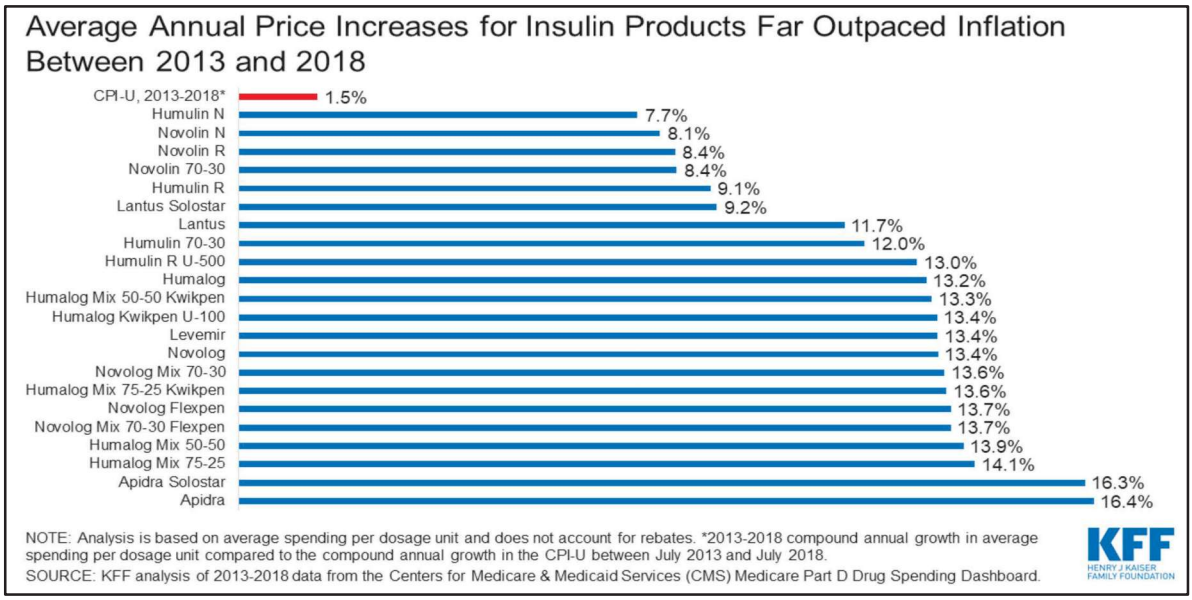
10. Figure 3 shows how Defendant Novo Nordisk has raised the price of its insulin product Levemir from 2006-2021.

Figure 3: Rising List Prices of Novo Nordisk's Levemir, 2006-2021



11. Figure 4 shows the price increases for all three Manufacturer Defendants' diabetes medications compared to inflation, from 2013-2018.

Figure 4: Insulin prices vs. inflation, 2013-2018



II. PARTIES

A. Plaintiff

12. Plaintiff Baltimore City Board of School Commissioners, which operates a system of public schools in Baltimore City commonly known as the Baltimore City Public School System or Baltimore City Public Schools (City Schools), is a Maryland entity vested with the authority to bring suit and be sued under Md. Education Code Ann. § 3-101 and Md. Education Code Ann. § 3-104, headquartered at 200 E. North Ave., Baltimore, MD 21202. City Schools offers health insurance to more than 9,000 employees and their dependents. One of the benefits it offers them is paying a substantial share of the purchase price of their pharmaceutical drugs, including the diabetes medications at issue in this complaint ("the at-issue insulins").

13. Between August 2017 and August 2024, City Schools paid millions of dollars more for the at-issue diabetes medications for its employees and their dependents that it otherwise would have spent but for Defendants' Insulin Pricing Scheme.

14. Any increase in spending has a detrimental effect on Plaintiff's overall budget and, in turn, negatively impacts its ability to educate students. The Insulin Pricing Scheme has had such an effect.

15. During the Class Period, City Schools contracted directly with and directly paid one or more Defendants (including through one or more PBM Defendants' mail order pharmacies), one or more of the at-issue diabetes medications, In connection with those direct purchases, City Schools paid more for at-issue drugs than it otherwise would have paid had Defendants not engaged in the conduct complained of in this Complaint. City Schools will continue to purchase the at-issue diabetes medications in the future.

16. With this lawsuit, Plaintiff seeks to recover the losses it has suffered due to Defendants' Insulin Pricing Scheme.

B. DEFENDANTS

The Manufacturer Defendant Entities

17. Defendant **Eli Lilly and Company ("Eli Lilly")** is an Indiana corporation with its principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. Eli Lilly manufactures, promotes, and distributes several at-issue diabetes medications, including: Humulin N, Humulin R, Humalog, Trulicity, and Basaglar.

18. Defendant **Sanofi-Aventis U.S. LLC ("Sanofi")** is a Delaware limited liability company with its principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi manufactures, promotes, and distributes pharmaceutical drugs nationwide, including Lantus, Apidra, Toujeo, and Soliqua.

19. Defendant **Novo Nordisk Inc. ("Novo Nordisk")** is a Delaware corporation with its principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey 08536. Novo Nordisk manufactures, promotes, and distributes several at-issue diabetes medications nationwide, including Novolin R, Novolin N, Novolog, Levemir, Victoza, Tresiba, and Ozempic.

20. References in this complaint to the "Manufacturer Defendants" or "Manufacturers" refer collectively to Eli Lilly, Sanofi, and Novo Nordisk.

21. In furtherance of their Insulin Pricing Scheme, all the Manufacturer Defendants self-report artificial, inflated "list prices" for their at-issue drugs to companies such as First DataBank, Medi-Span, and Red Book, which publish those list prices nationwide in compendia of drug prices. These "list prices" are often called the drugs' Wholesale Acquisition Cost or "WAC." 42 U.S.C. § 1395w-3a(c)(6). The Manufacturer Defendants self-report WAC for publication

knowing that payment and reimbursement for those drugs for employer self-funded health plans, by pharmacies, and patients are pegged to that fictitious inflated price. Within the statute of limitations period, Plaintiff and all members of the proposed Class purchased at-issue drugs at inflated prices pegged to WAC.

The PBM Defendant Entities

a. ***Defendant CVS Caremark Entities***

22. Defendant **CVS Health Corporation ("CVS Health")** is a Delaware corporation with its principal place of business at One CVS Drive, Woonsocket, Rhode Island 02895. In November 2018, CVS Health acquired a major health insurer, Aetna, Inc., becoming the first conglomerate to bring all of the following within one corporate family: a major health insurer, PBMs, a mail-order pharmacy, and retail pharmacy chains. In its capacity as a PBM, CVS Caremark has the largest market share of any PBM based on total prescription claims managed, representing around 40% of the national market.

23. CVS Health directly or indirectly owns all the stock of defendants CVS Pharmacy, CVS Specialty Pharmacy, Caremark Rx, L.L.C., Caremark, L.L.C. and CaremarkPCS Health, L.L.C. CVS Health sets the overarching policy and strategy across this entire CVS Health family, including the policies and strategies for the at-issue drugs that give rise to the claims in this case. All CVS Caremark executives ultimately report to the executives at CVS Health, including to the President and CEO of CVS Health. In public filings, documents, and statements, CVS Health presents the other defendant CVS Caremark entities as a "diversified health services company" that "works together across our disciplines." In their day-to-day operations, the CVS Caremark Defendants function as a single business enterprise. CVS Health sets the overarching policy and strategy across the entire CVS Health family.

24. In annual reports for at least the last decade, CVS Health (or its predecessor[3]) has repeatedly, continuously, and explicitly stated that CVS Health itself:

a. "[D]esign[s] pharmacy benefit plans that minimize the costs to the client while prioritizing the welfare and safety of the clients' members and helping improve health outcomes;"[4]

b. "[N]egotiate[s] with pharmaceutical companies to obtain discounted acquisition costs for many of the products on [CVS Health's] drug lists, and these negotiated discounts enable [CVS Health] to offer reduced costs to clients;"[5] and

c. "[U]tilize[s] an independent panel of doctors, pharmacists and other medical experts, referred to as its Pharmacy and Therapeutics Committee, to select drugs that meet the highest standards of safety and efficacy for inclusion on [CVS Health's] drug lists."[6]

25. CVS Health also brags that it lowers the cost of the at-issue drugs. For example, in 2016, CVS Health announced a new program to "reduce overall spending in diabetes," available in all states, to "help the company's pharmacy benefit management (PBM) clients . . . *lower pharmacy costs [for diabetes medications]* …. " (emphasis added).[7] Similarly, in 2017, CVS Health bragged that: "CVS Health pharmacy benefit management (PBM) strategies reduced trend for commercial clients to 1.9 percent per member per year, the lowest in five years. Despite manufacturer price increases of near 10 percent, *CVS Health* kept drug price growth at a minimal 0.2 percent."

26. Defendant **CVS Pharmacy, Inc. ("CVS Pharmacy")** is a wholly owned

[3] Until 2014, CVS Health was known as "CVS Caremark."

[4] CVS Caremark/CVS Health, Annual Reports (Form 10-K) (Dec. 31, 2009-2022).

[5] CVS Caremark/CVS Health, Annual Reports (Form 10-K) (Dec. 31, 2009-2013).

[6] CVS Caremark/CVS Health, Annual Reports (Form 10-K) (Dec. 31, 2009-2022).

[7] CVS HEALTH, *CVS Health Introduces New "Transform Diabetes Care" Program to Improve Health Outcomes and Lower Overall Health Care Costs* (Dec. 13, 2016), https://cvshealth.com/newsroom/press-releases/cvs-health-introduces-new- transform-diabetes-care-program-improve-health.

subsidiary of defendant CVS Health and a Rhode Island corporation, with its principal place of business at the same location as defendant CVS Health. CVS Pharmacy owns and operates tens of thousands of pharmacies nationwide that dispense and receive payment for the at-issue diabetes medications.

27. Defendant **Caremark Rx, L.L.C** (f/k/a Caremark Rx, Inc.), is a wholly owned subsidiary of defendant CVS Pharmacy. It is a Delaware limited liability company with its principal place of business at the same location as defendants CVS Pharmacy and CVS Health. Caremark Rx, L.L.C. provides PBM and mail- order pharmacy services.

28. Defendant **Caremark, L.L.C** is a subsidiary of defendant Caremark Rx, L.L.C. It is a California limited liability company, with its principal place of business at the same location as defendants CVS Pharmacy, CVS Health, and Caremark Rx, L.L.C. Caremark, L.L.C provides PBM and mail- order pharmacy services.

29. Defendant **CaremarkPCS Health, L.L.C.** ("CaremarkPCS Health"),is a subsidiary of defendant CVS Health. It is a Delaware limited liability company, with its principal place of business at the same location as defendant CVS Health. It provides pharmacy benefit management services.

30. Defendant **Zinc Health Ventures, LLC** is a Delaware limited liability company with its principal place of business at the same location as defendant CVS Health. Zinc is a group purchasing organization ("GPO") or "rebate aggregator." Zinc negotiates with drug manufacturers for rebates on prescription drugs, on behalf of CVS Caremark, including for at-issue diabetes medications.

31. Defendant **Zinc Health Services, L.L.C.** is a Delaware limited liability company

with its principal place of business at the same location as defendant CVS Health. Zinc Health Services, L.L.C. is a group purchasing organization ("GPO") or "rebate aggregator," which negotiates with drug manufacturers for rebates on prescription drugs for CVS Caremark, including for at-issue diabetes medications.

32. Defendant "**CVS Specialty Pharmacy"** are limited liability companies whose principal places of business are at the same location as defendant CVS Health. CVS Specialty pharmacy provides specialty pharmacy services, focusing on medications that are high-cost, require special handling, or are administered by injection or infusion, including at-issue diabetes medications.

33. As a result of interlocking directorships and shared executives, defendants Caremark Rx, LLC, CVS Pharmacy, and CVS Health are directly involved in the conduct control of defendants the management, operations, and business decisions of defendants CaremarkPCS Health, L.L.C., CVS Specialty Pharmacy, Zinc Health, and Caremark, LLC, as they relate to the at-issue drugs, manufacturer rebates for these medications, and their inclusion in formularies.

34. CVS Health directly or indirectly owns all the stock of CVS Pharmacy, CVS Specialty Pharmacy, Caremark Rx, L.L.C., Caremark, L.L.C. and CaremarkPCS Health, L.L.C.

35. All the executives of CaremarkPCS Health, L.L.C., Caremark, L.L.C., Caremark Rx, L.L.C., CVS Specialty Pharmacy, and CVS Pharmacy ultimately report to the executives at CVS Health, including to the President and CEO of CVS Health.

36. In public filings, documents, and statements, CVS Health present its affiliates—including CVS Pharmacy, CVS Specialty Pharmacy, CaremarkPCS Health, L.L.C, Caremark, L.L.C., Zinc Health, and Caremark Rx, L.L.C.—as divisions or departments of one unified

"diversified health services company" that "works together across our disciplines." In their day-to-day operations, these entities function as a single business enterprise.

37. References in this complaint to "CVS Caremark" refer collectively to all the defendant CVS Caremark entities identified above.

38. CVS Caremark is named as a Defendant in its capacities as a PBM and as a retail, specialty, and mail-order pharmacy.

39. At all times relevant, CVS Caremark has had express agreements with Novo Nordisk, Sanofi, and Eli Lilly regarding: (a) the price of the at-issue drugs; (b) Manufacturer payments for sales of those medications; and (c) placement of Manufacturers' at-issue in CVS Caremark's formularies.

b. ***The PBM Defendant Express Scripts Entities***

40. Defendant **Evernorth Health, Inc.** ("Evernorth"), formerly known as Express Scripts Holding Company, is a Delaware corporation with its principal place of business AT One Expressway, St. Louis, Missouri 63121.[8] In 2018, Evernorth merged with the multinational health insurance company Cigna. As a result, the Evernorth corporate family now controls prescription drug pricing and availability for the approximately 15 million Cigna members in the United States. Evernorth directly or indirectly owns all the stock of Express Scripts Administrators, LLC, Accredo Health, Ascent Health, Medco Health Solutions, Inc., ESI Mail Pharmacy Service, Inc., Express Scripts Pharmacy, Inc. and Express Scripts, Inc.

41. In annual reports filed with the SEC over the last decade, Evernorth has repeatedly and explicitly:

[8] Until 2021, Evernorth Health, Inc. conducted business under the name Express Scripts Holding Company. For the purposes of this Complaint "Evernorth" refers to Evernorth Health, Inc. and Express Scripts Holding Company.

- Acknowledged that it is directly involved in its affiliated companies' PBM services, acting as "one of the largest PBMs in North America";

- Bragged that it "provid[es] products and solutions that … assist in controlling cost" and "evaluat[es] drugs for … value and price to assist clients in selecting a cost-effective formulary" and "works with clients [and] manufacturers … to manage costs in the pharmacy benefit chain …." [9]

42. Defendant **Express Scripts, Inc.** is a Delaware corporation and a wholly owned subsidiary of Defendant Evernorth with its principal place of business at the same location as Evernorth. Express Scripts, Inc. is the immediate or indirect parent of the Express Scripts pharmacy and Express Scripts PBM defendants named in this Complaint.

43. Defendant **Express Scripts Administrators, L.L.C.** is a Delaware limited liability company and a wholly owned subsidiary of defendant Evernorth with its principal place of business is at the same location as Evernorth. Express Scripts Administrators, LLC provides pharmacy benefit management services.

44. Defendant **Medco Health Solutions, Inc.** ("Medco") is a Delaware Corporation with its principal place of business at the same address as Evernorth. Before merging with Express Scripts, Medco was, along with Express Scripts, one of the largest PBMs in the United States. Through the merger, all of Medco's PBM and mail-order pharmacy functions were combined into Express Scripts. The combined company (Medco and Express Scripts) all of Medco's payor customers becoming Express Scripts' customers. The combined company covered over 155 Americans at the time of the merger. In testimony before the Senate Judiciary Committee at the time of the merger in December 6, 2011, David Snow, then the CEO of Medco, represented that "the merger of Medco and Express Scripts will result in immediate savings to our clients and, ultimately, to consumers. This is because our combined entity will achieve even greater

[9] Express Scripts Annual Reports (Form 10-K) (Dec. 31, 2009-2019).

purchasing volume discounts [i.e., Manufacturer Payments] from drug manufacturers and other suppliers."[10] At the same time, the then-CEO of Express Scripts, George Paz, bragged that the merger would "[g]enerat[e] greater cost savings for patients and plan sponsors."[11]

45. Defendant **ESI Mail Pharmacy Service, Inc.** is a Delaware corporation and a wholly owned subsidiary of Defendant, with its principal place of business at the same location as Evernorth.

46. Defendant **Express Scripts Pharmacy, Inc.** is a Delaware corporation and a wholly owned subsidiary of Defendant Evernorth, with its principal place of business at the same location as Evernorth. The company provides mail-order pharmacy services.

47. Defendant **Ascent Health Services L.L.C. ("Ascent")** is a limited liability company with its principal place of business is offshore, at Muhlentalstrasse 36, 8200 Schaffhausen, Switzerland. Ascent Health is a group purchasing organization ("GPO") or "rebate aggregator" which negotiates with drug manufacturers for rebates on prescription drugs for Express Scripts entities, including for at-issue diabetes medications. Express Scripts co-owns Ascent and appoints three out of the five members of Ascent's Board of Directors.

48. Defendant **Accredo Health Group, Inc. ("Accredo Health")** is a Delaware corporation and is a wholly owned subsidiary of Defendant Evernorth. Accredo Health's principal place of business is at 1640 Century Center Parkway, Suite 101, Memphis Tennessee 38134. Accredo Health provides specialty pharmacy services.

49. Collectively, the defendant entities identified above are referred to as the "Express

[10] Transcript available at https://www.judiciary.senate.gov/imo/media/doc/11-12- 6SnowTestimony.pdf (last visited Apr. 5, 2024).

[11] Transcript available at https://www.judiciary.senate.gov/imo/media/doc/11-12- 6PazTestimony.pdf (last visited Apr. 4, 2024).

Scripts" Defendants.

50. Evernorth directly or indirectly owns all the stock of Express Scripts Administrators, LLC, Accredo Health, Ascent Health, Medco Health Solutions, Inc., ESI Mail Pharmacy Service, Inc., Express Scripts Pharmacy, Inc. and Express Scripts, Inc.

51. All Express Scripts executives ultimately report to Evernorth, including its CEO.

52. As a result of interlocking directorships and shared executives, defendants Evernorth and Express Scripts, Inc. are directly involved in the conduct of and control of the other Express Script Defendants' operations and management and business decisions related to at-issue diabetes medications, manufacturer rebates for these medications, and their inclusion in formularies.

53. Express Scripts is named as a Defendant in its capacities as a PBM and as a retail, specialty, and mail-order pharmacy. In its capacity as a PBM, Express Scripts controls at least 30% of the PBM market in the United States and contracts with approximately 65,000 retail chain and independent pharmacies, representing more than 98% of all retail pharmacies in the country.

54. At all relevant times, Express Scripts CVS has had express agreements with the Manufacturer Defendants regarding: (a) the price of the at-issue drugs; (b) Manufacturer payments for sales of those medications; and (c) placement of Manufacturers' at-issue in CVS Caremark's formularies.

c. ***The PBM Defendant Optum Entities***

55. Defendant **UnitedHealth Group, Inc**. **("UnitedHealth Group")** is a Delaware corporation with its principal place of business at 990 Bren Road East, Minnetonka, Minnesota 55343. UnitedHealth Group is a diversified managed healthcare company that owns the insurer UnitedHealthcare, the PBM OptumRX, and a mail-order pharmacy operation used by approximately 26 million UnitedHealthcare members in the United States. UnitedHealth Group controls the

entire drug payment chain for these 26 million Americans. UnitedHealth Group is directly involved in shaping the policies for its affiliated companies' PBM services, formulary construction, and pharmacy operations as they relate to the at-issue drugs. UnitedHealth Group brags that its PBM, OptumRx, "works directly with pharmaceutical manufacturers to secure discounts that lower the overall cost of medications and create tailored formularies—or drug lists …. [and] then negotiate[s] with pharmacies to lower costs at the point of sale . . ." UnitedHealth Group's 2022 annual reports state plainly that it is "involved in establishing the prices charged by retail pharmacies, determining which drugs will be included in formulary listings and selecting which retail."[12]

56. **Defendant Optum, Inc.** is a subsidiary of UnitedHealth Group. It is a Delaware corporation with its principal place of business at 11000 Optum Circle, Eden Prairie, Minnesota 55344. Optum, Inc. manages further subsidiaries that administer pharmacy benefits, including OptumInsight, OptumHealth and OptumRx," the CEOs of which all report directly to Optum, Inc.

57. Defendant **OptumRx, Inc**. is a California corporation with its principal place of business at 7 Technology Drive, Irvine, California 92618. OptumRx, Inc. operates as a subsidiary of OptumRx Holdings, LLC, which, in turn, operates as a subsidiary of Defendant Optum, Inc. OptumRx, Inc. provides the PBM and mail-order pharmacy services.

58. Defendant **OptumInsight, Inc. ("OptumInsight")** is a Delaware corporation with its principal place of business at 1 Optum Circle, Eden Prairie, MN 55344. OptumInsight role in the Insulin Pricing Scheme has included conducting analyses to advise the other Defendants about the

[12] UnitedHealth Group Annual Report (Form 10-K) (FYE Dec. 31, 2018); UnitedHealth Group Annual Report (Form 10-K, Ex. 21) (FYE Dec. 31, 2021); UnitedHealth Group Annual Report (Form 10-K, Exhibit 21) (FYE Dec. 31, 2022).

scheme's profitability.

59. Defendant **Emisar Pharma Services L.L.C. ("Emisar")** is a Delaware limited liability company with its principal place of business in Ireland. Emisar is a group purchasing organization ("GPO") or "rebate aggregator" that negotiates with drug manufacturers for rebates on prescription drugs for UnitedHealth Group's PBM business, including for at-issue diabetes medications. Emisar is a wholly owned indirect subsidiary of UnitedHealth Group.

60. Collectively, the defendant entities identified above are referred to as the "Optum" Defendants."

61. As a result of interlocking directorships and shared executives, UnitedHealth Group is directly involved in the conduct of and control of the other Optum Defendant entities' operations, management, and business decisions related to the at-issue drugs, formulary construction, negotiations, and mail-order pharmacy services.

62. UnitedHealth Group directly or indirectly owns all the stock of Optum, Inc., OptumRx, Inc., and OptumInsight. In their day-to-day operations, these entities function as a single business enterprise. The public filings, documents, and statements of UnitedHealth Group present its subsidiaries, including Optum, Inc., OptumRx, Inc., and OptumInsight as divisions, departments, or "segments" of a single company that is "a diversified family of businesses" and that "leverages core competencies" to "help[] people live healthier lives and helping make the health system work better for everyone."[13] All Optum Defendant executives ultimately report to the executives, including the CEO, of UnitedHealth Group.

63. Optum is named as a Defendant in its capacities as a PBM and as a mail- order pharmacy.

[13] UnitedHealth Group, Quarterly Report (Form 10-Q) (Mar. 31, 2017).

64. At all relevant times, Optum has had express agreements with Novo Nordisk, Sanofi, and Eli Lilly regarding: (a) the price of the at-issue drugs; (b) Manufacturer payments for sales of those medications; and (c) placement of Manufacturers' at-issue drugs in CVS Caremark's formularies.

65. At all relevant times, Optum has had express had express agreement Novo Nordisk, Sanofi, and Eli Lilly regarding the price of the at-issue drugs, manufacturer payments to for sales of those medications, sales of the Manufacturers' at-issue drugs through Optum's mail-order pharmacy, and placement of those Manufacturers' diabetes medications in Optum's formularies.

III. JURISDICTION AND VENUE

A. Subject Matter Jurisdiction

66. This Court has subject-matter jurisdiction over the RICO claims in this complaint pursuant to 28 U.S.C. § 1331, 28 U.S.C. 18 U.S.C. § 1332(d), and 18 U.S.C. § 1964(c). The Court has supplemental jurisdiction over the state law claims in this complaint pursuant to 28 U.S.C. § 1367.

67. During the Class Period, the Manufacturer Defendants sold, shipped, and paid kickbacks in connection with the at-issue insulins, the PBM Defendants received kickbacks in connection with such sales, and the PBM Defendants sold and shipped the at-issue insulins via their mail order pharmacies, in a continuous and uninterrupted flow of interstate commerce which included sales of the at-issue drugs in this District and throughout the United States and kickbacks from the proceeds of such sales. Defendants' conduct had a direct, substantial, and reasonably foreseeable effect on interstate commerce in the United States, including in this District.

B. Personal Jurisdiction

68. This Court has personal jurisdiction over each Defendant because each Defendant

has transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the scheme and conspiracy alleged in this complaint throughout the United States, including in this District.

69. The Court also has personal jurisdiction over all Defendants under 18 U.S.C. § 1965(b) because "the ends of justice" require national service so that all members of the nationwide RICO enterprises described in this complaint are brought before the Court in a single action for a single trial.

C. Venue

70. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c) and 18 U.S.C. . § 1965 because each Defendant transacts business in, is found in, and/or has agents in this District, and because some of the actions giving rise to the complaint took place or had their ultimate injurious impact in this District.

IV. DRUG PRICING IN THE UNITED STATES

A. Key Players in Drug Pricing

71. As relevant in this complaint, the marketplace for at-issue drugs has three key players: the drug manufacturers, health plan sponsors, and the PBMs.

1. *Drug Manufacturers (pharmaceutical companies)*

72. Drug manufacturers—like defendants Eli Lilly, Sanofi, and Novo Nordisk—own the patents rights and develop prescription drug medications. In addition, they also produce (or contract with others to produce), market, and sell prescription medications. And they set the "list price" for their prescription drugs, a price often called the drug's Wholesale Acquisition Cost or

"WAC."[14]

2. ***Health Plan Sponsors (or "payers")***

73. Most Americans purchase health insurance from a health plan—which may be a government-sponsored plan (such Medicare or Medicaid), a direct-purchase commercial plan (such as a plan from UnitedHealth, Aetna, Cigna, Blue Cross Blue Shield, or Kaiser Permanente), a union- or employer-sponsored plan, or a multi-employer Taft-Hartley trust.

74. Employer-sponsored plans are the most common. Most Americans are enrolled in an employer-sponsored health plan. Many of these the employer directly covers the cost of each claim (or the employer's share of that cost) as it arises instead of contracting with an insurance company which becomes responsible for paying claims.

75. City Schools and all School District Class Members operate employer self-funded plans.

76. One of the benefits provided by the vast majority of health plans—whether governmental, commercial, or employer-sponsored—is some form of prescription drug benefit that covers the at issue drugs (diabetes medications), subject to patients' deductibles and copays. City Schools and all the members of the proposed School District Class all offer a prescription drug benefit to their members that includes the at-issue drugs.

3. Pharmacy Benefit Managers (PBMs)

77. Health plans rarely themselves administer the prescription drug benefits they offer. Instead, they typically contract with a third-party, known as a "pharmacy benefit" manager (a "PBM") to perform that function.

[14] The related term "Average Wholesale Price" (AWP) is the published benchmark price for sales by wholesalers to retailers (such as pharmacies and hospitals). It is generally around twenty percent higher than WAC.

78. PBMs are positioned at the center of the drug distribution chain—between manufacturers, health plans, pharmacies, and patients. PBMs began, in the late 1950s, as providers of claims processing and administrative services. Over time, their services have expanded. Today, PBMs act as intermediaries between almost all the other entities in the pharmaceutical supply chain, providing a range of services that often include:

a. Processing prescription drug claims;

b. Establishing terms for prescribing, dispensing, and insured patients' use of medications. Typically, this includes creating and enforcing requirements for "prior authorization," dosage or supply limits, and "step therapies" (requirements that limit members' access to certain drugs until they have tried lower cost drugs). This PBM function is often called "utilization review" or "utilization management."

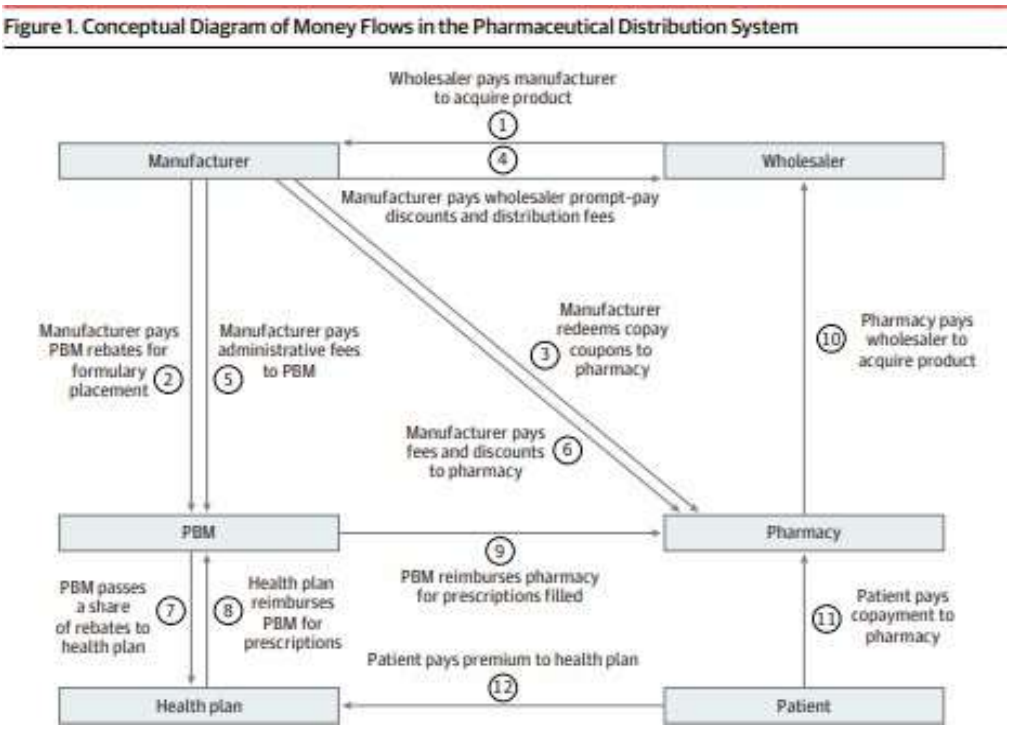
c. Providing mail-order pharmacy services;

d. Designing "formularies" (the list of prescription medications approved for use and coverage under a specific health plan); and

e. Negotiating drug prices for plan sponsors with manufacturers and pharmacies.

79. Graphically presented, the flow of money in the prescription drug distribution system typically looks like this:

Figure 5



B. Plaintiff and all other Class Members both retain PBMS as their agents or fiduciaries to negotiate with the Manufacturer Defendants for the best prices for the at-issue drugs and are direct purchasers of those drugs from PBM mail-order pharmacies.

80. The PBM Defendants tout their specific expertise and dedication to reducing prescription drug costs in order to gain business from health plan sponsors, including Plaintiff and the other Class Members. Lacking the resources or pharmaceutical expertise necessary to develop their own formularies, Plaintiff and all members of the proposed School District Class generally rely on PBM Defendants to develop formularies and negotiate the best prices for the at-issue drugs.

81. Each PBM Defendant offers mail order pharmacy services for the at-issue drugs. Plan sponsors, like Plaintiff and all other Class Members, directly purchase the at-issue drugs from those pharmacies owned by the PBM Defendants, including their mail-order pharmacies.

And because of Defendants' Insulin Pricing Scheme, Plaintiff and all other Class Members have overpaid for those purchases of the at-issue drugs.

82. Each Manufacturer Defendant and each PBM Defendant intended and foresaw that Plaintiff and the other Class Members would substantially overpay by purchasing the at-issue drugs from PBM mail order pharmacies at prices based on the Defendant Manufacturers' artificially inflated list prices, pursuant to the Defendants' Insulin Pricing Scheme.

83. But for Defendants' Insulin Pricing Scheme, the at-issue drugs that Plaintiff and the other Class Members have paid the PBMs for would have been lower priced and Plaintiff and the other Class Members would have paid less for them.

C. How Defendants' Insulin Pricing Scheme Works

84. Generally speaking, competition drives down prices as sellers try to win business. But Defendant Manufacturers have consistently *raised* the price of their at-issue drugs to attract PBM business—using *higher* prices to garner more sales—to the detriment of health plan sponsors like Plaintiff and the members of the proposed School District Class.

85. The Defendant Manufacturers have achieved this bold feat by colluding with the PBM Defendants—through racketing activity and deceptive and unfair trade practices, including illegal kickbacks that the Manufacturer Defendants pay to the PBM Defendants for preferred placement in the PBM Defendants' formularies and in return for which the PBM Defendants (a) give the Manufacturer Defendants favored treatment in their formularies, (b) protect the Manufacturer Defendants from price competition, and (c) abdicate their own role in resisting the Manufacturer Defendants' price hikes.

86. The Manufacturer and PBM Defendants jointly debuted their Insulin Pricing Scheme about a decade ago, at the same time as the advent of "exclusive" formularies.

87. For many years, PBMs operated essentially "open" formularies: in administering prescription drug plans for health plan sponsors, they offered a choice of nearly all FDA-approved medications. In particular, they did not use non-clinical reasons to exclude drugs from their formularies. But starting around 2012, in what Caremark recognized as a "bold move" at the time, the PBMs boldly changed their approach. They began excluding even clinically effective drugs from their formularies for purely commercial reasons. And they started demanding that if a manufacturer wanted its medications included in a formulary, or in a preferred position in a formulary, the manufacturer had to pay to play: the PBMs began demanding "rebates," that is, illegal kickbacks. The "rebate" (or kickback) payments are typically calculated as a percentage of WAC. And thus, was born what the Federal Trade Commission calls the Defendants' joint "chase-the-rebate-jack-the-price" strategy, their Insulin Pricing Scheme. See FTC Complaint (Nov. 26, 2024) (attached as Exhibit A).[15]

88. The first move in this scheme was the PBM Defendants' realization that they could extract more from the Manufacturer Defendants—by threatening to exclude a manufacturer's drug from formularies unless the manufacturer agreed to pay a bribe (a "rebate"). And because the PBMs serve as gatekeepers—they develop the lists of drugs that their "client" health plans will cover—manufacturers did not idly dismiss that threat. Patients primarily take only the drugs that are on their plan's PBM-created formulary. Accordingly, for a drug manufacturer, losing access to a plan's formulary means losing access to nearly all patients covered by that plan. In the case of a large plan, having a drug excluded by a PBM from a plan's formulary means the loss of thousands or millions of prescription orders. And so, to preserve their market positions, the

[15] Redactions in the FTC's complaint attached as Exhibit A were made by the FTC before public disclosure.

manufacturers agreed to pay "rebates."

89. The second move in this scheme was the PBM Defendants' realization that, given the deliberate opacity of prescription drug pricing, which they have worked hard to maintain, if they could persuade the Manufacturer Defendants to pay "rebates," they (the PBMs) could keep a sizeable share of these "rebates" for themselves without passing them on to health plan sponsors and plan members, who would be none the wiser. And they realized that these "rebates" could be even further disguised by calling them "administrative discounts" or "service fees" and by narrowly defining "rebates" in their contracts with plan sponsors, so that almost all Manufacturers Payments would be also outside of plan sponsors' audit rights, making them secret.[16] Similarly, PBMs' revenues from "rebates" are not disclosed in their quarterly SEC filings.

90. According to David Dross, a pharmacy-benefits consultant who has been cited in Senate testimony, administrative fees can amount to 25-30% of total payments from drug companies like the Manufacturer Defendants.[17] Express Scripts revealed in a 2017 lawsuit that it filed against one drug manufacturer that it kept 13 times more in administrative fees than it passed back to its clients through acknowledged "rebates."[18] A recent study by the Pew Charitable Trusts

[16] As used in this complaint, "Manufacturers Payments" refer to all payments or financial benefits of any kind conferred by drug manufacturers to PBM Defendants (or a subsidiary, affiliated entity, or group purchasing organization or rebate aggregator acting on the PBM's behalf). Manufacturer Payments include rebates, administrative fees, inflation fees, pharmacy supplemental discounts, volume discounts, price or margin guarantees, price concessions, indirect purchase fees and rebates, and any other form of consideration exchanged.

[17] David Dross, *Will Point-of-Sale Rebates Disrupt the PBM Business*?, Mercer (July 31, 2017), https://www.mercer.us/our-thinking/healthcare/will-point-of-sale-rebates -disrupt-the-pbm-business.html.

[18] *Express Scripts Lawsuit Should Raise Everyone's Eyebrows,* Nat'l Prescription Coverage Coalition, http://nationalprescriptioncoveragecoalition.com/express-scripts-lawsuit-should-raise-everyones-eyebrows/ (last visited Oct. 1, 2024). According to Express Scripts' complaint, it entered "rebate agreements" with the drug manufacturer, which required the manufacturer to pay Express Scripts far more in "administrative fees" than the manufacturer paid in "formulary rebates." *Id.*

estimated that, between 2012 and 2016, the amount of administrative and other fees that the PBMs received from the Manufacturers tripled, reaching more than $16 billion.[19]

91. The third move in the Defendants' scheme was the Manufacturer Defendants' realization that, if they were going to pay "rebates," under whatever label, *they* could benefit too—if the "rebates" were negotiated and paid as a percentage of (their already fictitious) list prices (WAC prices). As long as "rebates" and WAC move in tandem—with WAC pricing increasing at the same time and by an increment at least as large as "rebates"—then not only would the PBMs profit from rebates, so would the drug manufacturers. And indeed, both would be incentivized to continually *raise* WAC prices—to increase revenue for the drug manufacturer while at the same time increasing rebates for the PBMs. Neither the Manufacturer Defendants nor the PBM Defendants were concerned that, with WAC pricing tied not just to the size of rebates but also to the drug prices paid by plan sponsors (and patients), plan sponsors (and patients who, in this case, are also employees) would be harmed.

92. The fourth move toward putting the Defendants' Insulin Pricing Scheme in place was the PBM Defendants' agreement not to resist Manufacturers' price hikes for at-issue drugs—to the detriment of their clients (plan sponsors like Plaintiff and all School District Class Members).

93. An example will make this Insulin Pricing Scheme clearer. Consider an at-issue drug with a list price of $100, for which a PBM has negotiated a 40% rebate with a drug manufacturer. If that drug manufacturer needed to compete for formulary status by increasing the rebate paid to a PBM, which was threatening to exclude the drug unless the rebate increased, the drug

[19] *The Prescription Drug Landscape, Explored*, Pew Charitable Trusts, (Mar. 8, 2019), https://www.pewtrusts.org/en/research-and-analysis/reports/2019/03/08/the-prescription-drug-landscape-explored.

manufacturer could raise the WAC price to $120 and increase the rebate percentage to fifty percent. That would increase the rebate from $40 to $60. But the drug manufacturer would not be any worse off—because while the WAC and the rebate amounts change (from $100 to $120 and from $40 to $60, respectively), the spread between them would remain the same ($60). The drug manufacturer would keep the same $60 even as the PBM's share increased from $40 to $60. But payors would be the losers—because the cost of the drug *to them*, pegged to *WAC pricing* (which has increased from $100 to $120) goes up. In fact, as between the drug manufacturer, the PBM, and the plan sponsor (and its members), only the plan sponsor (and its members) are losers. *They* absorb the price hike. It makes *them* spend more. By contrast, it enriches both PBMs and drug manufacturers (who, by increasing list price, both increase revenue and, by securing a place in a PBM's formulary, also increase sales). In short, the Insulin Pricing Scheme allows the Defendant Manufacturers to preserve or increase sales (and market share) without reducing prices (and, in fact, perversely, by increasing prices) *and* without offering a better product (the at-issue medications have not changed); it also enriches the PBMs. It is a classic kickback scheme.

94. The results have been significant. The existence and success of the collusion and scheme are shown by, among other things:

a. The "near one-to-one relationship between rising rebates and rising list prices for branded prescription drugs," over the past decade, including for the at-issue diabetes medications. Neeraj Sood, et al. USC Leonard D. Schaeffer Center Health Pol'y & Econ., *The Association Between Drug Rebates and List Prices* 2020), https://healthpolicy.usc.edu/wp-content/uploads/2020/02/ SchaefferCenter_ RebatesListPrices_WhitePaper.pdf [https://perma.cc/Q3WT-Y8SR].

b. The equivalence of the at-issue drugs within their categories (rapid-acting or long-acting). Patients generally do not need to take one specific brand of insulin over another to treat their diabetes, and health plans largely do not need to cover all the drugs. These market conditions should yield lower insulin costs for health plans. They have not. That is probative of collusion.

c. Even when lower list price diabetes medications are available, Defendants collude to

exclude them in favor of higher list price versions. In a July 9, 2024, report by the FTC found that "some rebate contracts explicitly premise high rebates on the exclusion" of generics.[20] The FTC highlighted a rebate agreement for Defendant Manufacturer Sanofi's at-issue diabetes medication Lantus, showing:

> rebates premised on (1) preferred positioning over other competing products on a formulary or formulary tier (that is, the rebating manufacturer is one of several, one of few, or "1 of 1" in the competitive category); (2) "additional" rebates to specifically exclude competing manufacturers of competitive products from the formulary; and (3) "additional" rebates for implementing "brand step" requirements, meaning that patients must try and fail the preferred brand before being able to try the competing brand products.[21]

Similarly, on July 23, 2024, the House Committee on Oversight and Accountability issued its own report documenting how, in return for high rebates, the Defendant PBMs exclude competitors' "lower priced prescriptions such as cheaper generics."[22]

d. When new biosimilar or generic medications have entered the market, the PBM Defendants have often excluded them from their formularies. Asked in 2019, for a Congressional hearing, why Express Scripts would not include both costly *and* lower-priced insulin medications on its formulary Amy Bricker, former President of Defendant Express Scripts, explained: "We'll receive less discount [rebates] in the event we do that."[23]

e. One of Novo Nordisk's Vice Presidents has admitted that "low WAC/low rebate [insulins] don't stand a chance in this system."

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[20] *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 1, Interim Staff Report, FTC at 68 (July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

[21] *Id.* at 67.

[22] Staff of H. Comm. on Oversight and Accountability at 51, 118th Cong., Rep. on The Role of Pharmacy Benefit Managers in Prescription Drug Markets, House 3 (2024), https://oversight.house.gov/wp-content/uploads/2024/07/PBM-Report-FINAL-with-Redactions.pdf ("House Report").

[23] Questions for the Record Responses of Amy Bricker, Comm. on Energy and Commerce, Hearing on Priced Out of Lifesaving Drugs: Getting Answers on the Rising Cost of Insulin (Apr. 10, 2019), https://www.congress.gov/116/meeting /house/109299/witnesses/HHRG-116-IF02-Bio-BrickerA-20190410-U2.pdf, ¶¶ 1345-46, 1354-55.

D. Defendants' *Insulin Pricing* Scheme is a Deceptive and Unfair Trade Practice, Intended to Mislead Health Plan Sponsors (and Patients).

95. To conceal their Insulin Price Scheme, the PBM Defendants have repeatedly deceptively bragged that they *reduce* prices for diabetes medications for the benefit of health plan sponsors (and patients):

a. In 2016, Glen Stettin, Senior Vice President and Chief Innovation Officer at Express Scripts, acknowledged in an interview with a national publication that "[d]iabetes is wreaking havoc on patients, and it is also a runaway driver of costs for payors" but misrepresented that Express Scripts "helps our clients and diabetes patients prevail over cost and care challenges created by this terrible disease." Mr. Stettin also claimed that Express Scripts "broaden[s] insulin options for patients and bend[s] down the cost curve of what is currently the costliest Class of traditional prescription drugs."[24]

b. In its Annual Report in November 2010, CVS Caremark represented that it was focused on diabetes to "help us add value for our PBM clients and improve the health of plan members . . . a PBM client with 50,000 employees whose population has an average prevalence of diabetes could save approximately $3.3 million a year in medical expenditures."[25]

c. In a public statement in November 2012, CVS Caremark represented that formulary decisions related to insulin products "is one way the company helps manage costs for clients."[26]

d. In a 2017 CBS News interview, Express Scripts' CEO misrepresented that Express Scripts was "absolutely transparent" about the Manufacturer Payments that it receives and that payors "know exactly how the dollars flow" with respect to those payments.[27]

e. In April 2019, CVS Caremark's Chief Policy and External Affairs Officer falsely claimed that: "We negotiate the best possible discounts off the manufacturers' price on

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[24] Angela Mueller, *Express Scripts Launches Program to Control Diabetes Costs*, St. Louis Bus. J. (Aug. 31, 2016), https://www.bizjournals.com/stlouis/news/2016/08 /31/express-scripts-launches-program-to-control.html.

[25] 151 CVS Caremark 2010 Annual Report, https://s2.q4cdn.com/447711729/files/doc_financials/annual/cvs-ar-2010.pdf.

[26] *Diabetes Epidemic Growing*, CBS News, (June 22, 2010), https://www.cbsnews. com/news/diabetes-epidemic-growing/

[27] CBS News, *Express Scripts CEO Tim Wentworth Defends Role of PBMs in Drug Prices* (Feb 7, 2017), https://www.cbsnews.com/news/express-scripts-tim- wentworth-pbm-rising-drug-prices-mylan-epipen-heather-bresh/ (last visited Apr. 17, 2024).

behalf of employers, unions, government programs, and beneficiaries that we serve."[28]

f. Dr. Sumit Dutta, SVP and Chief Medical Officer of OptumRx, testified before the U.S. Congress in the April 2019 hearing that for "insulin products . . . we negotiate with brand manufacturers to obtain significant discounts off list prices on behalf of our customers."[29]

g. In May 2023, Optum Rx's CEO, Heather Cianfrocco told the U.S. Senate Committee on Health, Education, Labor and Pensions that Optum RX "has been at the forefront of efforts to improve access to affordable insulin. . . ."[30]

h. The main PBM trade association, the industry-funded Pharmaceutical Care Management Association ("PCMA") touts PBMs as "the only entity in the prescription drug supply and payment chain dedicated to reducing drug costs" and (contradicting the PBM representatives' Congressional testimony), that "when new manufacturers enter the market at a lower list price, PBMs use the competition to drive costs down."[31]

i. On an Express Scripts' earnings call in February 2017, CEO Tim Wentworth stated: "Drugmakers set prices, and we exist to bring those prices down."[32] And the same year, Wentworth went on CBS News to falsely deny that PBMs play any role in rising drug prices, stating that PBMs work to "negotiate with drug companies to get the prices down."[33]

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[28] *Priced Out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin* ¶¶ 714-18, Hearing Before the H. Subcomm. on Oversight and Investigations, 116th Cong. (2019), https://www.congress.gov/116/meeting/house/109299/documents/HHRG-116-IF02-Transcript-20190410.pdf (hereinafter, "Priced Out of a Lifesaving Drug"). Priced Out of a Lifesaving Drug, ¶¶ 714-18.

[29] *Id.* at 903-06.

[30] Heather Cianfrocco Written Testimony, *The Need to Make Insulin Affordable for All Americans* (May 10, 2023), https://www.help.senate.gov/imo/media/doc/Cianfrocco%20Written%20Testimony%20HELP%20Committee%20_Final.pdf.

[31] PCMA, *PBMs Reduce Insulin Costs: PBMs are working to improve the lives of patients living with diabetes and their families,* https://www.pcmanet.org/insulin- managing-costs-with-increasing-manufacturer-prices/ (last visited Apr. 17, 2024).

[32] [1]Samantha Liss, *Express Scripts CEO Addresses Drug Pricing 'Misinformation'*, St. Louis Post-Dispatch (Feb. 17, 2017), https://www.stltoday.com/business/local/ express-scripts-ceo-addresses-drug-pricing-misinformation/article_8c65cf2a-96ef- 5575-8b5c-95601ac51840.html (last visited Apr. 17, 2024).

[33] CBS News, *Express Scripts CEO Tim Wentworth Defends Role of PBMs in Drug Prices* (Feb. 7, 2017), https://www.cbsnews.com/news/express-scripts-tim- wentworth-pbm-rising-drug-prices-mylan-epipen-

j. Larry Merlo, head of CVS Caremark sounded a similar refrain in February 2017: "Any suggestion that PBMs are causing prices to rise is simply erroneous."[34]

k. During the April 2019 Congressional hearings, when asked if PBM-negotiated rebates and discounts were causing the insulin price to increase, OptumRx's Chief Medical Officer Sumit Dutta answered, "we can't see a correlation just when rebates raise list prices."[35]

l. Amy Bricker—then with Express Scripts, now with CVS—testified before Congress in 2019, "I have no idea why the prices [for insulin] are so high, none of it is the fault of rebates."[36]

m. A 2017 audit conducted by a local governmental entity on Defendant OptumRx related to its PBM activities from 2013 to 2015 concluded that the auditor was unable to verify the percentage of rebates OptumRx remitted to its client payor because OptumRx would not allow the auditor access to its rebate contracts.[37]

96. The PBMs have also imposed gag clauses on pharmacies and other participants in the distribution chain to prevent discovery of the Pricing Scheme.

97. The Manufacturer Defendants have likewise deceptively engaged in a pattern of misleading statements and omissions about the reasons for price hikes and they have concealed their anticompetitive behaviors. For example:

a. In April 2019, the Defendant Manufacturers urged Congress that the PBMs were solely to blame for insulin prices—because PBMs' demands for rebates in exchange for formulary placement. That was false. In January 2021, the Senate Finance Committee issued a report with findings that contradict the notion that but for the cost of rebates

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heather-bresh/ (last visited Apr. 17, 2024).

[34] Lynn R. Webster, *Who Is To Blame For Skyrocketing Drug Prices?*, THE HILL (July 27, 2017, 11:40 AM), https://thehill.com/blogs/pundits-blog/healthcare/344115-who- is-to-blame-for-skyrocketing-drug-prices (last visited Apr. 17, 2024).

[35] *Priced Out of a Lifesaving Drug* at lines 1019-22.

[36] *Id.* at lines 1016-17.

[37] Laura Rogers & Stacey Thomas, Broward County Florida, Audit of Pharmacy Benefit Management Services Agreement, No. 18-13 (Dec. 7, 2017), available at https://cragenda.broward.org/docs/2018/CCCM/20180109_555/25990_2017_1212%20Exh1_OptumRx%20-%20Revised%20Item.pdf (last visited Apr. 24, 2024).

prices would be lower: Eli Lilly has reported a steady increase in Humalog revenue for more than a decade—from $1.5 billion in 2007 to $3 billion in 2018. In short, revenues from Humalog sales have *increased* notwithstanding rebates.

b. Senate investigators have also found that Manufacturers are responsible for suppressing competition, thus raising prices. The Manufacturers have placed clauses in their contracts with PBMs that "stipulate terms" that health care sponsors, like Plaintiff and members of the Class, "must follow regarding factors such as formulary placement and competition from other drugs in the same therapeutic Class."[38]

c. The Manufacturer Defendants know that the prices paid by health plan sponsors, patients, and pharmacies for their at-issue diabetes medications are pegged to the fictitious and inflated WAC prices they self-report to publishing compendia. Despite this knowledge, that that is virtually the only price information they make public. They conceal information related to the net price they receive for the at issue drugs (after rebates and other Manufacturer Payments they extend to PBMs and wholesalers).

E. Background on Diabetes Medications

98. In healthy people without diabetes, the pancreas secretes the hormone insulin, which controls the rate at which food is converted to blood glucose. But when insulin is lacking or when cells stop responding to insulin, blood sugar stays in the bloodstream, leading to diabetes.

99. There is no cure for diabetes, and untreated it can cause serious health problems such as heart disease, stroke, kidney disease, vision loss, nerve damage, life-threatening infections, and amputations. In 2021, diabetes was the eighth leading cause of death in the United States and the leading cause of kidney failure, adult-onset blindness, and lower-limb amputations.

100. For many patients, the only way to manage their diabetes is with injections of insulin medications. More than 8 million Americans depend on insulin medications for their survival.

101. The three Manufacturer Defendants produce nearly all insulins all insulins available in the United States.

[38] Senate Insulin Report at 40.

102. The earliest insulin was derived from animals and went on the market in the 1920s. Until the 1980s, it was the only treatment for diabetes. But while effective, animal-derived insulin created the risk of allergic reaction. This risk was reduced in 1982 when Eli Lilly introduced the first synthetic insulin— also called "human insulin". Compared to animal-derived insulin, recombinant human insulins are cheaper to mass-produce. Eli Lilly marketed this insulin as Humulin.

103. In the mid-1990s, Eli Lilly introduced the first "analog" insulin—a laboratory grown, genetically modified form of human insulin, which is released under the brand name Humalog (generic name lispro).

F. The At-Issue Drugs

104. Figure 6 shows the at-issue diabetes drugs currently available in the U.S. market These are the "at-issue drugs" in this case:

Figure 6: "at-issue" Diabetes Medications

Insulin Type	Action	Name	Manufacturer	FDA Approval	List Price
Human	Rapid-Acting	Humulin R	Eli Lilly	1982	$178 (vial)
		Humulin R U-500	Eli Lilly	1982	$689 (pens)
		Novolin R	Novo Nordisk	1991	$165 (vial), $312 (pens)
Intermediate		Humulin N	Eli Lilly	1982	$178 (vial), $566 (pens)
		Humulin 70/30	Eli Lilly	1989	$178 (vial), $566 (pens)
		Novolin N	Novo Nordisk	1991	$165 (vial), $312 (pens)
		Novolin 70/30	Novo Nordisk	1991	$165 (vial), $312 (pens)
Analog	Rapid-Acting	Humalog	Eli Lilly	1996	$342 (vial), $636 (pens)
		Novolog	Novo Nordisk	2000	$347 (vial), $671 (pens)
		Apidra	Sanofi	2004	$341 (vial), $658 (pens)
	Pre-Mixed	Humalog 50/50	Eli Lilly	1999	$93 (vial), $180 (pens)
		Humalog 75/25	Eli Lilly	1999	$99 (vial), $140 (pens)
		Novolog 70/30	Novo Nordisk	2001	$203 (vial), $246 (pens)
	Long-Acting	Lantus	Sanofi	2000	$340 (vial), $510 (pens)
		Levemir	Novo Nordisk	2005	$370 (vial), $555 (pens)
		Basaglar (Kwikpen)	Eli Lilly	2015	$392 (pens)
		Toujeo (Solostar)	Sanofi	2015	$466 (pens), $622 (max pens)
		Tresiba	Novo Nordisk	2015	$407 (vial), $610–$732 (pens)
Type 2 Medications	GLP-1 Agonists	Trulicity	Eli Lilly	2014	$1,013 (pens)
		Mounjaro	Eli Lilly	2022	$1,068 (pens)
		Victoza	Novo Nordisk	2010	$813 (2 pens), $1,220 (3 pens)
		Xultophy	Novo Nordisk	2016	$1,295 (pens)
		Ozempic	Novo Nordisk	2017	$1,022 (pens)
		Rybelsus	Novo Nordisk	2019	$1,029 (30-

					day tablets)
		Adlyxin	Sanofi	2016	Discontinued (2023)
		Soliqua	Sanofi	2016	$928 (pens)

G. Recent Price Cuts

105. As a result of the American Rescue Plan of 2021, the Manufacturer Defendants were facing penalties, beginning in 2024, unless they lowered their list prices. And several of the Defendant Manufacturers' at-issue drugs—including Humalog, Novolog, and Lantus—were especially at risk for penalties—because of their up to sevenfold list price increases over time. The Defendant Manufacturers projected incurring hundreds of millions of dollars in Medicaid liability unless they lowered their list prices (WACs). So,

a. On March 1, 2023, Lilly announced that it would reduce the list price of high WAC Humalog by 70%, as well as set the price of its low WAC Humalog at $25 a vial.

b. On March 14, 2023, Novo announced that it would reduce the list price of high WAC Novolog by 75% and Levemir by 65%. And,

c. On March 16, 2023, Sanofi announced that it would reduce the list price of high WAC Lantus by 78% and Apidra by 70%.

106. These three announcements (the "Price Cuts") were prospective price cuts. They do not mitigate damages already incurred by payors like Plaintiff and the members of the proposed School District Class.

107. In addition, these Price Cuts were limited. The Defendant Manufacturers cut prices for their most at-risk products—diabetes drugs that had undergone dramatic price increases over time, not necessarily for newer at-issue drugs that, although introduced with inflated WACs, had not yet undergone dramatic price increases because they had been on the market much less time.

108. To make matters worse, on November 8, 2023, before the 65% price cut for its long-acting insulin Levemir had taken effect, Novo Nordisk announced that it would be *discontinuing*

Levemir in the United States, citing manufacturing constraints, formulary-placement issues, and "alternative treatments" for patients. Levemir is the *only* branded, long-acting insulin product for which Novo Nordisk announced a list price reduction and the *only* long-acting insulin FDA-approved for pregnancy. Yet, Novo Nordisk is discontinuing Levemir—before allowing the price reduction to take effect—with supply disruptions beginning in early 2024, followed by formal discontinuation of the Levemir FlexPen vial by the end of 2024.

V. TOLLING OF THE STATUTE OF LIMITATIONS

A. Continuing Violations/Separate Accrual Doctrine

109. Defendants' conduct, giving rise to Plaintiff's and the other Class Members' claims, is ongoing; the Insulin Pricing Scheme remains in effect. Accordingly, under the continuing violations/separate accrual doctrine, this action is timely because the last act evidencing the continuing practice falls within the applicable limitation periods.

B. Fraudulent Concealment Tolling

110. All applicable statutes of limitation have also been tolled by Defendants' knowing and active fraudulent concealment and denial of the facts alleged herein throughout the period relevant to this action.

C. Estoppel

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111. Defendants owed Plaintiff and all Class Members a continuous duty to disclose the true character, quality, and nature of the list prices upon which their payments for insulin were based.

112. Based on the foregoing, Defendants are estopped from relying on any statutes of limitations in defense of this action.

D. Relation Back / American Pipe Tolling

113. Plaintiff and all Class Members assert claims herein arising out of the conduct, transactions, and occurrences set forth in the original complaints filed by FWK Holdings, LLC and Rochester Drug Cooperative, Inc., on March 31, 2020. *See FWK Holdings, LLC v. Novo Nordisk Inc. et. al*., 20-cv-3480 at ECF No. 1 ("FWK Complaint") and *Rochester Drug Cooperative, Inc. v. Eli Lilly and Co. et. al*., 20- cv-3426 at ECF No. 1 ("Rochester Complaint"). Plaintiff and the other Class Members are also encompassed by the Class definition in the FWK and/or Rochester Complaints and, accordingly, their claims were tolled pursuant to *American Pipe & Construction Company v. Utah*, 414 U.S. 538 (1974) and its progeny.

VI. INTERSTATE TRADE AND COMMERCE

114. During the Class Period, Defendants, directly or through one or more of their affiliates, sold the at-issue drugs throughout the United States in a continuous and uninterrupted flow of interstate commerce, including through and into this District.

115. The business activities of Defendants that are the subject of this action were within the flow of, and substantially affected, interstate trade and commerce.

116. Defendants' and their co-conspirators' conduct, including the marketing and sale of the sale of the at-issue drugs, did and was intended to have, a direct, substantial, and reasonably foreseeable anticompetitive effect upon interstate commerce within the United States.

117. Defendants' conduct as alleged in this Complaint has directly and substantially affected interstate commerce as Defendants deprived Plaintiff and the other Class Members of the benefits of free and open competition in the purchase of the at-issue drugs within the United States.

VII. ANTITRUST AND RICO INJURY

118. During the Class Period, Plaintiff and the other Class Members directly purchased the at-issue drugs from the Defendants. As a result of Defendants' unlawful scheme, Plaintiff and the other Class Members paid more for the at-issue drugs than they would have. This is a cognizable injury and constitutes compensable harm under the federal antitrust laws and the RICO statute.

119. As a result of Defendants' unlawful conduct, Plaintiff and the other Class Members have sustained, and continue to sustain, significant losses in the form of artificially inflated prices paid for the at-issue drugs and the retention by the PBM Defendants of the unearned rebates and fees that are not paid for the delivery of any service. The full amount of such damage will be calculated after discovery and upon proof at trial.

120. Further, the PBMs were and are the agents and/or fiduciaries of the Plaintiff and all School District Class Members in their role as intermediaries with the Manufacturer Defendants for the Plaintiff and all School District Class Members, and breached duties owed to the Plaintiff and all School District Class Members by taking kickbacks in the form of inflated payments from the Manufacturer Defendants in exchange for placing the at-issue drugs on their formularies.

121. Plaintiff and all School District Class Members were directly injured by the illicit scheme between the PBM Defendants and the Manufacturer Defendants both because they directly purchased at-issue drugs with artificially inflated prices from the Defendants' mail order pharmacies and because the Plaintiff and all School District Class Members hire the PBM Defendants to work on their behalf to obtain the best possible prices for prescription drugs and the illicit scheme undermined the agent and/or fiduciary relationship between the PBM Defendants and the members of the Class.

VIII. CLASS ACTION ALLEGATIONS

122. Plaintiff brings this action on behalf of themselves and all others similarly situated under Federal Rule of Civil Procedure 23(a), (b)(2) and (b)(3), as representatives of the following School District Class:

> All school systems and consortia of schools with self-funded health plans and their self-funded plans that purchased one or more of the at-issue drugs from one or more of the PBM Defendants within the limitations period.

123. Plaintiff believes there are hundreds of Class Members that are geographically dispersed throughout the United States. As a result, joinder of all members of the Class is impracticable.

124. Class Members are readily identifiable from information and records maintained by Defendants.

125. Plaintiff's claims are typical of the claims of all other Class Members.

126. Plaintiff and all Class Members were damaged by the same wrongful conduct by Defendants—i.e., as a result of Defendants' misconduct, these purchasers made insulin purchases at artificially inflated prices, and they will continue to do so in the future.

127. Plaintiff will fairly and adequately protect and represent the interests of the Class. Plaintiff's interests are coextensive with, and not antagonistic to, those of the other Class Members.

128. Counsel that representing Plaintiff are experienced in the prosecution of Class action litigation and have particular experience in RICO and antitrust cases involving pharmaceutical products.

129. Questions of law and fact common to the Class Members predominate over questions that may affect only individual Class Members because Defendants have acted on

grounds generally applicable to the entire Class. As a result, calculating aggregate damages for the Class as a whole is appropriate.

130. Questions of law and fact common to the Class include, but are not limited to:

i. Whether Defendants controlled and inflated the list price (WAC) of the at-issue drugs;

ii. Whether the Manufacturer Defendants engaged in a pattern and practice of paying illegal kickbacks, disguised as "rebates," to the PBM Defendants that created substantial spreads between the list and net prices;

iii. Whether the large list-to-net price spreads were intended to induce the PBM Defendants to give the Manufacturer Defendants' at-issue drugs favorable placement on the PBM Defendants' formularies;

iv. Whether the Manufacturer Defendants used artificially inflated list prices as a starting point for negotiating these kickbacks or "rebates" for the at-issue drugs;

v. Whether each Defendant conspired for the purpose of carrying out this pricing and kickback scheme;

vi. Whether Plaintiff and the other Class Members overpaid based on the artificial list prices for the at-issue drugs;

vii. Whether the Manufacturer Defendants copied their competitors' price increases such that all at-issue drugs were infected by the pricing and kickback scheme;

viii. Whether Defendants engaged in mail and wire fraud in carrying out their unlawful pricing and kickback scheme;

ix. Whether Defendants engaged in commercial bribery in violation of 18 U.S.C. § 1341.

x. Whether Manufacturer Defendants paid kickbacks to the PBM Defendants that provide ERISA benefit plan services to employer sponsored health benefit plans with the intention of influencing the choice of at-issue drugs to include in the benefit plan formularies that determine whether and to what extent a particular insulin is available to patients on favorable terms in violation of 18 U.S.C. § 1954;

xi. Whether Defendants engaged in commercial bribery in violation of the Travel Act, 18 U.S.C. § 1952;

xii. Whether Defendants were engaged in one or more "enterprises" within the meaning of the federal RICO statute;

xiii. Whether Defendants operated such RICO enterprise(s) through a pattern of racketeering activity including mail and wire fraud in violation of state law and 18 U.S.C. §§ 1341, 1343, 1952, and 1954.

xiv. Whether the alleged illegal conduct engaged in by Defendants comprised racketeering activity, in violation of federal RICO laws;

xv. Whether, and to what extent, Defendants' RICO violations caused injury to Plaintiff and the other Class Members in their business, trade, or property; and

xvi. Whether Defendants are liable to Plaintiff and the other Class Members for damages flowing from their misconduct.

xvii. Whether Defendants engaged in a kickback scheme and thereby committed commercial bribery;

xviii. Whether such conduct is a violation of Section 2(c) of the Robinson Patman Act.

131. Plaintiff and the other Class Members have all suffered, and will continue to suffer, harm and damages as a result of Defendants' unlawful and wrongful conduct. A Class action is superior to other available methods for the fair and efficient adjudication of this controversy under Rule 23(b)(3). Such treatment will permit a large number of similarly-situated school districts with self-funded prescription benefit plans to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the Class mechanism, including providing injured entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this Class action. Absent a Class action, most Class Members likely would find the cost of litigating their claims to be prohibitive and will have no effective remedy at law. The Class treatment of common questions of law and fact is also superior to multiple individual

actions or piecemeal litigation in that it conserves the resources of the courts and the litigants and promotes consistency and efficiency of adjudication. Additionally, Defendants have acted and failed to act on grounds generally applicable to Plaintiff and the Class and require Court imposition of uniform relief to ensure compatible standards of conduct toward the Class, thereby making appropriate equitable relief to the Class as a whole within the meaning of Rule 23(b)(2).

132. Plaintiff knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a Class action.

133. The Manufacturer Defendants concealed the at-issue drugs' net prices and prevented Plaintiff and the other Class Members from knowing what these prices were to ensure the Manufacturer Defendants would not have to meaningfully lower the net prices of those drugs. and the PBM Defendants would benefit from the spreads between the net and list prices. Put another way, Manufacturer Defendants' publication of their list prices, while concealing their net prices, is the basis for the quid pro quo with the PBM Defendants. Defendants' pricing scheme enabled the Manufacturer Defendants to offer the PBM Defendants large spreads on which to make profits in exchange for preferred formulary status. If the Manufacturer Defendants did not have these spreads to offer, they would have been forced to compete for preferred formulary status through lower list prices. Put simply, without the pricing schemes, the Manufacturer Defendants would have competed for PBM Defendants' business the way competitors do in healthy markets: by lowering the prices. Such competition would have benefited Plaintiff and the other Class Members, but instead of competing on lower prices, each Manufacturer Defendant competed on a larger spread.

134. To do so, Defendants closely guarded their pricing structures and sales figures for their at-issue drugs. Each Manufacturer Defendant kept secret the net prices it offered to the PBM

Defendants.

135. Each Defendant also concealed its fraudulent conduct by signing confidentiality agreements with those in the supply chain that knew the net prices.

136. In sum, each Defendant concealed that: (i) the list prices for at-issue drugs were fraudulently inflated, (ii) it was manipulating the list prices of at-issue drugs, (iii) the list prices bore no relationship to the prices paid for, or the pricing structure of, the at-issue drugs, and (iv) the net prices to the PBM Defendants were either held constant or else decreasing.

137. Defendants' publication of the list prices for at-issue drugs, combined with their concealment of their net prices, deceived Plaintiff and the other Class Members into believing that the at-issue drugs' list prices were reasonably related to the drugs' net prices.

138. Plaintiff and the Class relied on the representations regarding their list prices and paid for the at-issue drugs based on these inflated list prices to their detriment. Plaintiff and the Class continue to pay for the at-issue drugs based on their list prices. Such payments are fraudulent given the value of these drugs as evidenced by their true, net prices.

139. As a result of Defendants' scheme, Plaintiff and the other Class Members overpaid when purchasing at-issue drugs based on their list prices. No other entity in the drug supply chain sets these list prices and no other entity in the supply chain has the ability to change these list prices, on which Plaintiff's and other Class Members' payments for the at-issue drugs are directly based.

IX. CLAIMS FOR RELIEF

COUNT ONE
VIOLATIONS OF RICO, 18 U.S.C. § 1962(c)
(Against All Defendants on behalf of Plaintiff and the Class)

140. Plaintiff repeats and re-alleges paragraphs 1–139.

A. *Defendants are Culpable "Persons" Under RICO*

141. Plaintiff brings this count against Defendants, as identified below, on behalf of the Class and alleges violations of Section 1962(c) of RICO, 18 U.S.C. § 1962(c).

142. Plaintiff, the other Class Members, and each Defendant are all "persons," as that term is defined in 18 U.S.C. § 1961(3).

B *The Manufacturer-PBM Insulin Pricing RICO Enterprises*

143. For purposes of this claim, the RICO "enterprises" are associations-in-fact consisting of (a) one of the three largest PBMs—CVS Caremark, Express Scripts, or OptumRx—that administers purchases of the Manufacturer Defendants' at-issue drugs, including its directors, employees, and agents, and (b) one of the Manufacturer Defendants, including its directors, employees, and agents. These associations-in-fact enterprises are collectively referred to in this complaint as the "Manufacturer-PBM Insulin Pricing Enterprises."

144. For purposes of this claim, the RICO "enterprises" are associations-in-fact consisting of (a) one of the three largest PBMs—CVS Caremark, Express Scripts, or OptumRx—that administers purchases of the Manufacturer Defendants' at-issue drugs, including its directors, employees, and agents, and (b) one of the Manufacturer Defendants, including its directors, employees, and agents. These associations-in-fact enterprises are collectively referred to in this complaint as the "Manufacturer-PBM Insulin Pricing Enterprises."

145. Each of the Manufacturer-PBM Insulin Pricing Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common and/or shared purposes of selling, purchasing, and administering the at-issue drugs to Plaintiff and the other Class Members and deriving secret profits from these activities (the pricing and kickback scheme). These profits are greater than either the

Manufacturer Defendants or the PBM Defendants could obtain absent their fraudulent concealment of the substantial kickbacks misleadingly labeled as "rebates" or "fees" from the Manufacturer Defendants to the PBM Defendants.

146. As to each Enterprise, (i) there is a common communication network by which the particular Manufacturer Defendant and PBM Defendant respectively share information on a regular basis, and (ii) the particular Manufacturer Defendant and PBM Defendant function as continuing but separate units. At all relevant times, each Enterprise was operated and conducted by the particular Manufacturer Defendant and PBM Defendant for criminal and fraudulent purposes, namely, carrying out the kickback scheme.

147. Each Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common and/or shared purposes of selling, promoting, and recommending for purchase, and administering prescriptions for the at-issue drugs and deriving secret profits from these activities.

148. To accomplish this common purpose, Defendants systematically artificially inflated the list prices of the at-issue drugs and Manufacturer Defendants and systematically paid kickbacks—falsely labeled as rebates, administrative fees, and/or other payments or compensation—to PBM Defendants in exchange for exclusive and/or favorable placement of their at-issue drugs on the formularies maintained by the PBM Defendants on behalf of their respective clients. They did so willfully, and with knowledge that Class Members make payments directly based on the inflated list prices.

149. It is this scheme that is fraudulent. Manufacturer Defendants' benchmark prices are no longer a reasonable approximation of the actual price of at-issue drugs, and the Manufacturer-PBM Insulin Pricing Enterprises concealed the magnitude of the spreads between benchmark

prices and net prices from Plaintiff and the Class. The Manufacturer-PBM Insulin Pricing Enterprises also concealed from the public the purpose of these spreads: the spreads ultimately result in higher profits for the Manufacturer Defendants, through ensuring formulary access without requiring significant price reductions; and they result in higher profits for the PBM Defendants, whose earnings increase as the spread between list and net prices grows.

150. Each Manufacturer-PBM Enterprise also shares a common purpose of perpetuating use of insulin list prices as the basis payments in the pharmaceutical industry. With respect to the Manufacturer Defendants, these corporations would not be able to market large spreads to the PBM Defendants in exchange for favorable formulary positions without the use of the inflated list prices as the basis for plan sponsors' payments in the pharmaceutical industry. The PBM Defendants share this common purpose because, without the use of the inflated list prices, their profits on the spread between list and net prices would collapse.

151. As a result, PBM Defendants have, with the knowing and willful participation \and assistance of the Manufacturer Defendants, engaged in hidden profit-making schemes falling into four general categories: (i) they pocket what their plan sponsors clients pay them as service fees for processing prescriptions and operating mail order pharmacies; (ii) they keep the difference between what they pay pharmacies for drugs, which is negotiated as a percentage of list price plus dispensing costs, and what plan sponsors pay them, which is a higher percentage of list price plus dispensing costs; (iii) they profit from selling prescription drugs to plan sponsors through the mail order pharmacies that they own and operate; and (iv) they retain the entirety of undisclosed and/or hidden rebates they receive.

152. Each of the Manufacturer-PBM Insulin Pricing Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities

between each Manufacturer Defendant and each PBM Defendant that is an associate. As to each of the Manufacturer-PBM Insulin Pricing Enterprises, there is a common communication network by which each Manufacturer Defendant and each PBM Defendant share information on a regular basis, including information regarding the Insulin Drug list prices and net prices. As to each of the Manufacturer-PBM Insulin Pricing Enterprises, each Manufacturer Defendant and each PBM Defendant functioned as a continuing unit. At all relevant times, each of the Manufacturer-PBM Insulin Pricing Enterprises was operated by the specific Manufacturer Defendant and PBM Defendant for criminal purposes, namely, carrying out the pricing scheme.

153. At all relevant times, PBM Defendants have been aware of the Manufacturer-PBM Insulin Pricing Enterprises' conduct, have been knowing and willing participants in that conduct, and have reaped profits from that conduct. PBM Defendants strike rebate deals with Manufacturer Defendants to conceal the true net prices of the at-issue drugs and profit from the inflated list prices. PBM Defendants have represented to the public that the rebates they negotiate save plan sponsors (including Plaintiff and the other Class Members) money on prescriptions. But they have known that the increasing spreads did not and do not actually decrease the net prices of the at-issue drugs: the list prices were and are falsely inflated while the net prices have remained, more or less, constant. But for the Manufacturer-PBM Insulin Pricing Enterprises' common purpose of enlarging the hidden spreads between net and list price, PBM Defendants would have had the incentive to disclose the fraudulence of Manufacturer Defendants' list prices. By failing to disclose this information, PBM Defendants and Manufacturer Defendants perpetuated the conduct of the Manufacturer-PBM Insulin Pricing Enterprises.

154. Further, the PBM Defendants took instructions and commands from the Manufacturer Defendants regarding use of the at-issue drug list prices, not only so that they could

keep part of the spread, but also so as to continue to earn: (i) access rebates for placement of products on their formulary; (ii) market share rebates for garnering higher market share than established targets; (iii) administrative fees for assembling data to verify market share results; and (iv) other fees and grants in an effort to promote products.

155. In order to garner all of these fees from Manufacturer Defendants, each PBM Defendant and each Manufacturer Defendant meet on a regular basis to discuss Insulin Drug prices, spreads, marketing opportunities, and coordination of all of the above.

156. There is a common communication network between each PBM Defendant and each Manufacturer Defendant for the purpose of implementing the Insulin Pricing Scheme and for the exchange of financial rewards for PBM Defendants activities that benefit Manufacturer Defendants.

157. At all relevant times, each one of PBM Defendants was aware of the Insulin Pricing Scheme, was a knowing and willing participant in that scheme, and reaped profits from that scheme.

158. For purposes of this count, the Manufacturer-PBM Insulin Pricing Enterprises are further identified as follows:

1. *The Eli Lilly-PBM Enterprises*

159. The Eli Lilly-PBM Enterprises are three separate associations-in-fact consisting of Eli Lilly, including its directors, employees, and agents, and each of the PBM Defendants that administers purchases of Eli Lilly's Humalog, Humulin, and Basaglar, including its directors, employees, and agents: (1) the Eli Lilly-CVS Caremark association-in-fact enterprise; (2) the Eli Lilly-Express Scripts association-in-fact enterprise; and (3) the Eli Lilly-OptumRx association-in-fact enterprise. Each of the Eli Lilly-PBM Enterprises is an ongoing and continuing business

organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of exchanges kickbacks or "rebates" for preferred formulary positions for Eli Lilly's Humalog, Humulin, and Basaglar as treatments for Type 1and Type 2 diabetes to the exclusion of competitor products. Each of the Eli Lilly-PBM Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Eli Lilly and CVS Caremark, Eli Lilly and Express Scripts, and Eli Lilly and OptumRx. As to each of these Eli Lilly-PBM Enterprises, there is a common communication network by which Eli Lilly and CVS Caremark, Eli Lilly and Express Scripts, and Eli Lilly and OptumRx share information on a regular basis. As to each of these Eli Lilly-PBM Enterprises, Eli Lilly and CVS Caremark, Eli Lilly and Express Scripts, and Eli Lilly and OptumRx function as continuing but separate units. At all relevant times, each of the Eli Lilly-PBM Enterprises was operated and conducted by Eli Lilly and the specific PBM Defendant for criminal purposes, namely, carrying out the pricing and kickback scheme.

2. *The Novo Nordisk-PBM Insulin Pricing Enterprises*

160. The Novo Nordisk-PBM Insulin Pricing Enterprises are three separate associations-in-fact consisting of Novo Nordisk, including its directors, employees and agents, and each of the PBMs that administered purchases of Novo Nordisk's Fiasp, Novolog, Levemir, Novolin, and Tresiba, including its directors, employees, and agents: (1) the Novo Nordisk-CVS Caremark association-in-fact enterprise; (2) the Novo Nordisk-Express Scripts association-in-fact enterprise; and (3) the Novo Nordisk-OptumRx association-in-fact enterprise. Each of the Novo Nordisk-PBM Insulin Pricing Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of exchanges kickbacks or "rebates" for preferred formulary positions for Novo

Nordisk's Levemir, Tresiba, Novolin, Fiasp, and Novolog, as treatments for Type 1 and Type 2 diabetes to the exclusion of competitor products. Each of the Novo Nordisk-PBM Insulin Pricing Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Novo Nordisk and CVS Caremark, Novo Nordisk and Express Scripts, and Novo Nordisk and OptumRx. As to each of these Novo Nordisk-PBM Insulin Pricing Enterprises, there is a common communication network by which Novo Nordisk and CVS Caremark, Novo Nordisk and Express Scripts, and Novo Nordisk and OptumRx share information on a regular basis. As to each of these Novo Nordisk-PBM Insulin Pricing Enterprises, Novo Nordisk and CVS Caremark, Novo Nordisk and Express Scripts, and Novo Nordisk and OptumRx function as continuing but separate units.

161. At all relevant times, each of the Novo Nordisk-PBM Insulin Pricing Enterprises was operated and conducted by Novo Nordisk and the specific PBM Defendant for criminal purposes, namely, carrying out the pricing scheme.

3. *The Sanofi-PBM Insulin Pricing Enterprises*

162. The Sanofi-PBM Insulin Pricing Enterprises are three separate associations-in-fact consisting of Sanofi, including its directors, employees and agents, and each of the PBMs that administered purchases of Sanofi's Apidra, Lantus, and Toujeo, including its directors, employees, and agents, and Sanofi, including its directors, employees and agents: (1) the Sanofi-CVS Caremark association-in-fact enterprise; (2) the Sanofi-Express Scripts association-in-fact enterprise; and (3) the Sanofi-OptumRx association-in-fact enterprise. Each of the Sanofi-PBM Insulin Pricing Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of exchanges kickbacks or "rebates" for preferred formulary positions for Sanofi's Lantus,

Toujeo, and Apidra, as treatments for Type 1 and Type 2 diabetes to the exclusion of competitor products. Each of the Sanofi-PBM Insulin Pricing Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Sanofi and CVS Caremark, Sanofi and Express Scripts, and Sanofi and OptumRx. As to each of these Sanofi-PBM Insulin Pricing Enterprises, there is a common communication network by which Sanofi and CVS Caremark, Sanofi and Express Scripts, and Sanofi and OptumRx share information on a regular basis. As to each of these Sanofi-PBM Insulin Pricing Enterprises, Sanofi and CVS Caremark, Sanofi and Express Scripts, and Sanofi and OptumRx function as continuing but separate units. At all relevant times, each of the Sanofi-PBM Insulin Pricing Enterprises was operated and conducted by Sanofi and the specific PBM Defendant for criminal purposes, namely, carrying out the pricing and kickback scheme.

163. The Manufacturer-PBM Insulin Pricing Enterprises (Eli Lilly-CVS Caremark, Eli Lilly-Express Scripts, Eli Lilly-OptumRx, Novo Nordisk-CVS Caremark, Novo Nordisk-Express Scripts, Novo-Nordisk-OptumRx, Sanofi-CVS Caremark, Sanofi-Express Scripts, and Sanofi-OptumRx) knowingly made material misrepresentations, including omissions, to Class Members in furtherance of the fraudulent scheme regarding:

a. The net prices of the at-issue drugs;[39]

b. The reasons for the Insulin Drug price increases;

c. PBM Defendants' receipt of kickbacks in the form of purported rebates, fees, or other payments for formulary placement unconnected to services rendered;

d. The existence, purpose, and amount of the kickbacks and other monies paid to PBM Defendants;

[39] The Eli Lilly-PBM Enterprises made these misrepresentations with respect to Humalog, Humulin, and Basaglar. The Novo Nordisk-PBM Insulin Pricing Enterprises made these representations with respect to Fiasp, Novolog, Levemir,

e. The effect of the rebates, fees, and other payments on PBM Defendants' development, management, and administration of formularies;

f. The extent to which the net prices of the at-issue drugs departed from their artificially inflated list prices;

g. The extent to which the Manufacturer Defendants and the PBM Defendants negotiated the rebates discounting the list prices of the at-issue drugs in good faith and for a proper purpose;

h. Whether the rebates—as opposed to lower list prices—saved Plaintiff and the other Class Members and the general public money;

i. Whether the "preferred" formulary status of the at-issue drugs reflects the drugs' safety, efficacy, or cost-effectiveness, as determined by the PBM Defendants' formulary committees;

j. Whether the at-issue drugs would have been placed in "preferred" formulary positions absent the spreads;

k. Whether the "administrative fees" the Manufacturer Defendants paid to PBM Defendants were for administrative services performed by PBM Defendants in relation to the processing, invoicing, and collection of rebates; and Novolin, and Tresiba. The Sanofi-PBM Enterprises made these misrepresentations with respect to Apidra, Lantus, and Toujeo.

l. The extent to which the pricing schemes forced Plaintiff and the other Class Members to incur additional expenses for their Insulin Drug prescriptions.

164. The Manufacturer Defendants could not have accomplished the purposes of the Manufacturer-PBM Insulin Pricing Enterprises without the assistance of the PBM Defendants. For the Manufacturer Defendants to profit from the scheme, the PBM Defendants needed to agree not to resist WAC price hikes. And the PBM Defendants needed to convince plan sponsors, such as Plaintiff and the Class member to select their formularies, on which varying at-issue drugs were given favorable treatment. And the PBM Defendants did so by making material misrepresentations and omissions (including to Plaintiff, potential clients, and investors) that they secured lower prices and by omitting and concealing their kickbacks, rebates, fees, and scheme.

The lower prices were illusory, the result of a deliberate scheme to create large spreads without lowering net prices when in reality, The Manufacturer Defendants were inflating list prices to fund kickbacks to PBM Defendants for favorable formulary placement. Without these material misrepresentations and omissions and concealment, the Manufacturer-PBM Enterprise could not have achieved its common purpose.

165. The impacts of the Manufacturer-PBM Insulin Pricing Enterprises are still in place, i.e., the increased spreads between the benchmark and net prices of the at-issue drugs are still being maintained. As described herein, kickbacks are an essential part of the Manufacturer-PBM Insulin Pricing Enterprises and are embedded in the ongoing Insulin Drug prices. This conduct constitutes a threat of continued criminal activity.

166. The Manufacturer Defendants and PBM Defendants were each willing participants in the Manufacturer-PBM Insulin Pricing Enterprises, had a common fraudulent purpose and interest in the objective of the scheme, and functioned within a structure designed to effectuate the Enterprises' purposes, i.e., to increase profits for both Manufacturer Defendants and PBM Defendants through kickbacks to PBM Defendants and continued formulary status without net price reductions from Manufacturer Defendants, preserving and increasing Manufacturer Defendants' profits.

C. *The Manufacturer-PBM Insulin Pricing RICO Enterprises' Use of the U.S. Mails and Interstate Wire Facilities*

167. Each of the Manufacturer-PBM Insulin Pricing Enterprises engaged in and affected interstate commerce because they engage in the following activities across state boundaries: the sale, purchase and/or administration of the at-issue drugs; the setting of the prices of the at-issue drugs; and/or the transmission and/or receipt of sales and marketing literature; and/or the transmission to patients of individual prescriptions for the at-issue drugs by mail order

pharmacies; and/or the transmission and/or receipt of invoices, statements, and payments related to the use or administration of the at-issue drugs. During the Class period, the Manufacturer-PBM Insulin Pricing Enterprises participated administration of the at-issue drugs to millions of individuals located throughout the United States.

168. During the Class period, Defendants' illegal conduct and wrongful practices were carried out by an array of employees, working across state boundaries, who necessarily relied upon frequent transfers of documents and information and products and funds through the U.S. mails and interstate wire facilities.

169. The nature and pervasiveness of Defendants' pricing and kickback scheme, which was orchestrated out of the corporate headquarters of Defendants, necessarily required those headquarters to communicate directly and frequently by the U.S. mails and by interstate wire facilities between Manufacturer Defendants and PBM Defendants.

170. Most of the precise dates of Defendants' uses of the U.S. mails and interstate wire facilities (and corresponding RICO predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to these Defendants' books and records. Indeed, an essential part of the successful operation of the pricing scheme alleged herein depended upon secrecy, as alleged above. And Defendants took deliberate steps to conceal their wrongdoing. However, Plaintiff can generally describe the occasions on which the RICO predicate acts of mail fraud and wire fraud occurred, and how those acts were in furtherance of the pricing scheme.

171. Defendants' use of the U.S. mails and interstate wire facilities to perpetrate the pricing scheme involved thousands of communications throughout the Class period including, inter alia:

a. Marketing materials about the list prices for the at-issue drugs and the available spreads, which Manufacturer Defendants sent to PBM Defendants located across the

country;

b. Written and oral representations of the Insulin Drug list prices that the Manufacturer Defendants made at least annually and, in many cases, several times during a single year;

c. Thousands of written and oral communications discussing, negotiating, and confirming the placement of a Manufacturer Defendant's at-issue drugs on a particular PBM Defendant's formulary;

d. Written and oral representations regarding information or incentives designed to lessen the prices that each of the PBM Defendants paid for the at-issue drugs, and/or to conceal those prices or the pricing scheme;

e. Written communications, including checks, relating to rebates, kickbacks, or other financial inducements paid to each of the PBM Defendants to persuade them to advocate for one Manufacturer Defendant's Insulin Drug over a competitor's product;

f. Written and oral communications with U.S. government agencies and private insurers that fraudulently misrepresented what the list prices were, or that were intended to deter investigations into the true nature of the list prices or to forestall changes to reimbursement based on something other than list prices;

g. Written and oral communications with health insurers and patients;

h. Transmission of list prices from manufacturers to third parties;

i. Transmitting invoices, statements, and payments related to the use, administration, and/or purchase of the at-issue drugs;

j. Receipts of money on tens of thousands of occasions through the U.S. mails and interstate wire facilities—the wrongful proceeds of Defendants' pricing scheme; and

i. In addition to the above-referenced RICO predicate acts, Defendants' corporate headquarters have communicated through use of the U.S. mails and by interstate wire facilities with their various local headquarters or divisions, in furtherance of the pricing scheme. These mailings include certain documents referenced in this Complaint.

D. Conducting the RICO Enterprises' Affairs

172. During the Class period, each of the Manufacturer Defendants has exerted control over the Manufacturer-PBM Insulin Pricing Enterprises with which they were associated and, in violation of Section 1962(c) of RICO, each of the Manufacturer Defendants have conducted or

participated in the conduct of the affairs of those association-in-fact RICO enterprises, directly or indirectly. Such participation was carried out in the following ways:

a. Each of the Manufacturer Defendants has directly controlled the list prices for their respective at-issue drugs, which determine the amounts of rebates, administrative fees, and other payments PBM Defendants receive as compensation in exchange for formulary placement;

b. Each of the Manufacturer Defendants directly controlled the list prices of their at-issue drugs they publicly reported;

c. Each of the Manufacturer Defendants has directly controlled the creation and distribution of marketing, sales, and other materials used to inform each of PBM Defendants of the profit potential of its at-issue drugs;

d. Each of the Manufacturer Defendants has relied upon its employees and agents to promote the pricing scheme through the U.S. mails, through interstate wire facilities, and through direct contacts with providers and PBM Defendants; and

e. Each of the Manufacturer Defendants has controlled and participated in the affairs of the Manufacturer-PBM Insulin Pricing Enterprises with which it is associated by providing kickbacks falsely labeled as rebates, administrative fees, or other inducements to place that Manufacturer Defendant's Insulin Drug(s) on a PBM Defendant's formulary or advocate the use of a certain Insulin Drug. These inducements include the Manufacturer Defendants' payment to PBM Defendants of: (i) access rebates for placement of products on the PBM Defendants' formulary; (ii) market share rebates for garnering higher market share than established targets; (iii) administrative fees for assembling data to verify market share results; and (iv) other fees and grants. Although PBM Defendants typically agree to share rebates in some form with clients, they usually refuse to disclose specific rebate amounts to plan sponsors, such as Plaintiff and the other Class Members. Instead, the PBMs typically disclose rebates in an aggregate compared to performance standards, thereby preventing plan sponsors, including Plaintiff and the other Class Members, from learning the true number of rebates that the PBM Defendant has received in connection with the at-issue drugs. Such a lack of transparency obfuscates the delta between Manufacturer Defendants' list prices and their net prices so that plan sponsors, including Plaintiff and the other Class Members, have no way to ascertain whether the prices they are paying for the at-issue drugs are fair and competitive.

f. Manufacturer Defendants intended that PBM Defendants would (and did) distribute, through the U.S. mail and interstate wire facilities, promotional and other materials which claimed that rebates lowered drug costs for plan sponsors, like Plaintiff and the other Class Members;

g. Manufacturer Defendants represented to the general public, by stating the at-issue drugs' list prices without stating that these list prices differed substantially from those net prices offered to

h. PBM Defendants, that the at-issue drugs' list prices reflected or approximated true prices for those drugs; and

i. Manufacturer Defendants Published and announced collusive, artificially inflated list price increases and the reasons therefore, but concealing that the increases were to fund the kickbacks to the PBM Defendants to secure favorable, preferred, or exclusive formulary placement.

173. In violation of Section 1962(c) of RICO, each of the Manufacturer Defendants has conducted and/or participated in the affairs of each of the Manufacturer-PBM Insulin Pricing Enterprises with which they associated by reporting fraudulently inflated list prices for the at-issue drugs and by misrepresenting to Plaintiff and the other Class Members through the publication of their list prices that these list prices were reasonable bases for Plaintiff and the other Class Members' out-of-pocket payments, thereby inducing Plaintiff and other Class Members to pay inflated amounts for the at-issue drugs.

174. In addition, PBM Defendants specifically have conducted or participated in the conduct of the affairs of their association-in-fact RICO enterprises, by, among other things: (a) misrepresenting and/or concealing from Plaintiff, other Class Members, and the public the existence, amount, and purpose of the rebates, administrative fees, and/or other monies from Manufacturer Defendants; (b) misrepresenting and/or concealing the effect of the rebates, so-called administrative fees, and/or other monies from Manufacturer Defendants on the Insulin Drug list prices from Plaintiff, other Class Members, and the public; (c) accepting these ill-gotten rebates and/or fees in exchange for providing Manufacturing Defendants' at-issue drugs favorable placement on formularies, and (d) selling the at-issue drugs at artificially inflated prices directly to plan sponsors via their mail order pharmacies.

E. Defendants' Pattern of Racketeering Activity

175. Each of the Defendants has conducted and participated in the affairs of the respective Manufacturer-PBM Insulin Pricing Enterprises through a pattern of racketeering activity under 18 U.S.C. § 1961, and committed the following violations outlined below knowingly and with the intent to advance the scheme.

176. Defendants' pattern of racketeering has involved thousands, if not hundreds of thousands, of racketeering acts, and has occurred over the period from 2009 through the present. Each of these mailings and interstate wire transmissions constitutes a "racketeering activity" within the meaning of 18 U.S.C. § 1961(1). Collectively, these violations constitute a "pattern of racketeering activity," within the meaning of 18 U.S.C. § 1961(5), in which each Manufacturer Defendant and PBM Defendant intended to defraud Plaintiff.

177. All of Defendants' racketeering activities amounted to a common course of conduct, with a similar pattern and purposes. The kickbacks, misrepresentations and omissions, and separate uses of the U.S. mail and/or interstate wires by Defendants and the respective Manufacturer-PBM Insulin Pricing Enterprises in connection with the illegal schemes were substantially related, had similar intended purposes, involved similar participants and methods of execution, and had similar results affecting similar victims. The racketeering activity constitutes a threat of continuing criminal activity.

178. Defendants have committed the following predicate acts, all constituting racketeering activity under 18 U.S.C. § 1961.

a. *Unlawful Kickbacks for Benefit Plan Services*

179. More than 54 percent of the individuals in this country receive prescription drug benefits through their employers pursuant to an employee welfare benefit plan as defined in 29

U.S.C. §1002(1).

180. The PBM Defendants are legal persons who provide benefit plan services to most of these employee benefit plans.

181. In direct violation of 18 U.S.C § 1954, Manufacturer Defendants paid and PBM Defendants solicited and received fees and kickbacks with the intention of influencing the choice of the at-issue drugs to include in formularies that determine whether and to what extent a particular at-issue drugs are available to patients whose prescription drug benefits are provided, in whole or in part, pursuant to an employee welfare benefit plan, all in direct violation of 18 U.S.C. §1954, and therefore comprising racketeering activity by the under 18 U.S.C § 1961(1)(B).

b. *Unlawful Bribery in Violation of 18 U.S.C. §§ 1952, 666(a), 666(b)*

182. For each year during the Class Period, each of the Manufacturer Defendants paid and each of PBM Defendants solicited and accepted in excess of $5,000 in "rebates," "administrative fees," and other kickbacks from the sale of the at-issue drugs.

183. Such "rebates," "administrative fees," and other kickbacks were corruptly solicited, demanded, paid, and accepted for the purpose of influencing PBM Defendants to cause the at-issue drugs to be placed on the preferred drug formularies and to reward Manufacturer Defendants for doing so.

184. Given that, the pricing and kickback scheme adopted and implemented by the Manufacturer-PBM Insulin Pricing Enterprises constitute a violation of 18U.S.C. §§ 1952, 666(a), 666(b) and, as such, comprises racketeering activity under 18 U.S.C. § 1961(1)(B).

c. *Violations of the AKS Comprising Racketeering Activity under 18 U.S.C. § 1957*

185. The commercial kickbacks paid by Manufacturer Defendants to PBM Defendants in

connection with prescriptions funded in whole or in part by federal health care programs such as Medicare, Medicaid, and CHAMPVA totaled well over $10,000 per year and were deposited in financial institutions that included federally insured banks.

186. The commercial kickbacks paid by Manufacturer Defendants to PBM Defendants in connection with prescriptions funded in whole or in part by federal health care program such as Medicare, Medicaid, and CHAMPVA were paid and received with the corrupt and unlawful intention of purchasing, and in fact purchasing, formulary placement for the at-issue drugs and, as such, constituted ongoing violations of the AKS.

187. PBM Defendants knew that the payments that they received from Manufacturer Defendants were derived from payments solicited and received in violation of the AKS and such payments were, in fact, derived from kickback transactions in violation of the AKS.

188. The AKS is a criminal prohibition against payments made purposefully to induce or reward the referral or generation of federal health care business. The Act criminalizes a drug company's offer or payment of anything of value in return for a PBM's placing that manufacturer's drug in a favorable formulary position with respect to, in whole or part, a federal health care program. This includes a drug manufacturer's offer or payment to a PBM respecting private, nonfederal business that implicitly or explicitly requires that the PBM place the manufacturer's drug in a favorable position with respect to a federal health care program. The AKS extends not just to a drug manufacturer's payment, but also to the solicitation or acceptance of remuneration by PBMs.

189. The OIG and the Secretary of HHS have long warned that "[l]ump sum payments for inclusion in a formulary or for exclusive or restricted formulary status are problematic and should be carefully scrutinized." 68 F.R. 23731, at 23736 (2003).

190. The purported "discounts" or "rebates" afforded by PBM Defendants to Manufacturer Defendants do not fall within the safe harbor. First, they are neither "discounts" nor "rebates" alone, as they are accompanied by the quid pro quo of getting preferred formulary treatment. Second, the "discounts" or "rebates" do not reduce the manufacturer's net selling price—to the extent that the manufacturer has increased the benchmark price to make up for an increased "rebate," all that it has done is created a widened spread from which PBM Defendants can make more money. This is a Classic kickback.

191. The conduct of each of the Manufacturer-PBM Insulin Pricing Enterprises, as described herein, amounts to a violation of 18 U.S.C. § 1957 and is racketeering activity as defined in 18 U.S.C. 1961(1)(B).

d. ***Unlawful Bribery Under the Travel Act and AKS in Violation of 18 U.S.C. § 1952(a) and 42 U.S.C. § 1320a-7b(b)(2)***

192. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), each of the Manufacturer-PBM Insulin Pricing Enterprises have, in violation of 18 U.S.C. § 1952(a), used U.S. mail and wire facilities in interstate commerce to intentionally promote, manage, establish, carry on, and facilitate the unlawful activity of bribery under the laws of the United States and the laws of the state where committed. *See* 18 U.S.C. § 1952(b)(2).

193. Specifically, as alleged immediately above, through the U.S. mail and wire facilities in interstate commerce in violation of the AKS, each Manufacturer Defendant paid kickbacks to each of PBM Defendants, which PBM Defendants solicited and/or accepted, with the intention of purchasing, and in fact purchasing, formulary placement for at-issue drugs for which payment may be made in whole or in part under one or more federal health care programs.

e. ***Mail and Wire Fraud in Violation of 18 U.S.C. §§ 1341, 1343***

194. Each of the Defendants has conducted and participated in the affairs of their

respective Manufacturer-PBM Insulin Pricing Enterprises through a pattern of racketeering activity, including acts that are indictable under 18 U.S.C. § 1341, relating to mail fraud, and 18 U.S.C. § 1343, relating to wire fraud. Defendants' pattern of racketeering likely involved thousands, if not hundreds of thousands, of separate instances of use of the U.S. mails or interstate wire facilities in furtherance of their scheme or artifice to defraud for purposes of obtaining money or property. Each of these fraudulent mailings and interstate wire transmissions constitutes a "racketeering activity" within the meaning of 18 U.S.C. § 1961(1)(B). Collectively, these violations constitute a "pattern of racketeering activity," within the meaning of 18 U.S.C. § 1961(5), in which Defendants intended to defraud Plaintiff, other Class Members, and other intended victims of the pricing scheme.

195. Specifically, as outlined above, each of the at-issue drugs have been promoted through the mail and wires, thereby announcing to health plans, including Plaintiff and the other Class Members, each Manufacturer Defendant's artificially inflated list price increases but omitting the material fact that the reason for the increased list prices was to fund, increase, and/or recoup each Manufacturer Defendant's kickbacks to secure formulary placement. Moreover, Defendants have falsely and misleadingly called the kickbacks to PBM Defendants "rebates"—which have been publicly represented as lowering drug costs—when they are, in fact, bribes and kickbacks to PBM Defendants for formulary placement, which enabled each Manufacturer Defendant to sell the at-issue drugs at inflated prices.

196. Defendants' racketeering activities amounted to a common course of conduct, with similar patterns and purposes, intended to deceive Plaintiff and the other Class Members. Each separate use of the U.S. mails and/or interstate wire facilities employed by each of the Defendants was related, had similar intended purposes, involved similar participants and

methods of execution, and had the same results affecting the same victims, including Plaintiff and the other Class Members. Each of the Defendants has engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the respective Manufacturer-PBM Insulin Pricing Enterprises with which each of them is and was associated in fact.

F. Defendants' Motive

197. Defendants' motive in creating and operating the pricing scheme and conducting the affairs of the Manufacturer-PBM Insulin Pricing Enterprises described herein was to fraudulently obtain sales of and profits related to the at-issue drugs.

198. The pricing scheme was designed to, and did, encourage others, including health care providers, to advocate the use of Manufacturer Defendants' at-issue drugs. Thus, each of the Manufacturer Defendants used the pricing scheme to sell more of its drugs, thereby fraudulently gaining sales, marketplace share, and profits.

199. PBM Defendants used the pricing scheme to increase their profits by benefitting from larger spreads between the list prices and net prices of the at-issue drugs.

G. Damages Caused by Defendants' Pricing Scheme

200. Defendants' violations of federal law and their pattern of racketeering activity have directly and proximately caused Plaintiff and other Class Members to be injured in their business or property by overpaying for the at-issue drugs. Plaintiff and other Class Members each directly bought at-issue drugs from one or more of Defendants, and thus were directly and immediately harmed by Defendants' schemes. Defendants intended and foresaw that Plaintiff and other Class Members would pay substantial overcharges due to Defendants' pattern of racketeering activity.

201. Defendants sent billing statements through the U.S. mails or by interstate wire

facilities and reported the list prices and other information by the same methods in furtherance of their pricing scheme. Plaintiff and the other Class Members have overpaid for the at-issue drugs based on and/or in reliance on reported and false list prices. As previously explained, when a patient fills a prescription for one of the at-issue drugs at CVS Caremark, Express Scripts, or OptumRx, her health plan is responsible for a portion or nearly all of the medication's cost. And the health plans pay directly to CVS Caremark, Express Scripts, or OptumRx, members of the Manufacturer-PBM Insulin Pricing Enterprises.

202. The amount of each payment for an at-issue drug is tied directly to the Manufacturer Defendants' list prices. No other intermediary in the supply chain has control over or is responsible for the list prices on which payments are based. By setting the list prices of the at-issue drugs, Defendants are setting the prices Plaintiff and the other Class Members must pay. Therefore, when each Manufacturer Defendant artificially inflates each Insulin Drug's list price and then uses each Manufacturer-PBM Insulin Pricing Enterprises to sell those at-issue drugs, they also artificially inflate Plaintiff and other Class Members' payments for those drugs.

203. Though PBM Defendants could have used their control over the development, management, and administration of the formularies and prescription drug programs that their clients relied upon to drive down the prices for the at-issue drugs by forcing Manufacturer Defendants to lower their list prices, PBM Defendants instead leveraged their position to obtain the Manufacturer Defendants' kickbacks for their own financial benefit and contrary to the economic interests of their clients and plan members.

204. Rather than lower their prices to gain market share via formulary inclusion, Manufacturer Defendants instead engaged in a scheme with PBM Defendants to artificially inflate list prices in exchange for preferred formulary placement, shifting the cost of the kickbacks to

purchasers of the at-issue drugs such as Plaintiff and the other Class Members and sharing those financial benefits with the PBM Defendants.

205. Absent the payment of kickbacks, and their achievement through the at-issue drugs list price increases, Manufacturer Defendants would have been forced to compete for preferred formulary placement through lower prices, as they would in a legitimate market. As the gatekeepers in the supply chain, PBM Defendants could and would have used formulary placement (or exclusion) to penalize manufacturers who raised prices as Manufacturer Defendants did here, rather than perversely rewarding manufacturers who raised prices and inducing them to do so with favorable formulary placement.

206. But for the payment of kickbacks, and their achievement through list price increases, the at-issue drugs would have had a lower list price, and Plaintiff and the other Class Members would have paid less for the at-issue drugs. Plaintiff and the other Class Members have overpaid for the at-issue drugs purchased directly from the Defendants.

207. Defendants' racketeering activity directly and proximately caused Plaintiff and the other Class Members injuries because Plaintiff and other Class Members purchased the at-issue drugs directly from Defendants. Further, given that Plaintiff and the other Class Members were and are the most direct and immediate victims of the unlawful and fraudulent schemes, Plaintiff and the other Class Members are best situated to vindicate the law and seek recovery for the economic harm caused by Defendants based on the substantial overcharges for the at-issue drugs.

208. By virtue of these violations of 18 U.S.C. § 1962(c), under the provisions of Section 1964(c) of RICO, Defendants are jointly and severally liable to Plaintiff and the other Class Members for three times the damages that Plaintiff and the other Class Members have sustained, plus the costs of bringing this suit, including reasonable attorneys' fees.

209. By virtue of these violations of 18 U.S.C. § 1962(c), under the provisions of Section 1964(c) of RICO, Plaintiff and other Class Members further seek injunctive relief against Defendants for their fraudulent reporting of their list prices, plus the costs of bringing this suit, including reasonable attorneys' fees. Absent an injunction, the effects of this fraudulent conduct will continue. Plaintiff will continue purchasing the Manufacturer Defendants' at-issue drugs, and Plaintiff and the other Class Members will continue to pay based on Defendants' fraudulent benchmark prices. In a country where tens of thousands of citizens cannot afford their medications needed to treat diabetes, or where the expense of such drugs is a great burden on millions, and there is no cure for diabetes, any continuing fraudulent conduct is a serious matter that calls for injunctive relief as a remedy. Plaintiff will seek injunctive relief, including an injunction against Defendants, to prevent them from reporting benchmark prices that do not approximate their true net prices.

COUNT TWO
VIOLATIONS OF RICO, 18 U.S.C. § 1962(d)
(Against All Defendants on behalf of the all Plaintiff and the Class)

210. Plaintiff incorporates by reference the allegations contained in the preceding paragraphs.

211. Defendants have violated 18 U.S.C. § 1962(d) by agreeing and conspiring to violate 18 U.S.C. § 1962(c). The object of this conspiracy has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the 18 U.S.C. § 1962(c) Manufacturer-PBM Insulin Pricing Enterprises described previously through a pattern of racketeering activity.

212. Defendants have engaged in numerous overt and predicate unlawful and fraudulent acts, constituting a pattern of racketeering activity, in furtherance of the conspiracy. Defendants intended to engage in the schemes, resulting in Plaintiff and the other Class Members paying

substantial overcharges for the at-issue drugs. Defendants knew that their predicate acts were part of a pattern of racketeering activity and agreed to the commission of those acts to further the schemes outlined herein.

213. The nature of Defendants' acts, material misrepresentations, and omissions in furtherance of the conspiracy, as set forth in detail above, gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but that they were aware that their ongoing unlawful and fraudulent acts have been and are part of an overall pattern of racketeering activity.

214. Defendants have engaged (and continue to engage) in the commission of overt acts in furtherance of the Manufacturer-PBM Insulin Pricing Enterprise schemes, including the following unlawful racketeering predicate acts (as outlined in detail above):

- Multiple instances of unlawful bribery and kickbacks in violation of 18 U.S.C. §§ 666(a), 666(b), 1952, 1954, 1957, 1961(1), and 42 U.S.C. 1320a-7b(b)(2);
- Multiple instances of mail fraud in violation of 18 U.S.C. § 1341; and
- Multiple instances of wire fraud in violation of 18 U.S.C. § 1343.

215. Defendants' violations of the above federal laws and the effects thereof outlined in detail above are continuing and will continue. As a direct and proximate result of these violations, Plaintiff and the other Class Members have been injured in their business and property; Plaintiff and the other Class Members have made at least millions of dollars in overpayments for the at-issue drugs purchased directly from the Defendants that they would not have paid but for Defendants' conspiracies to violate 18 U.S.C. § 1962(c).

216. By virtue of these violations of 18 U.S.C. § 1962(d), Defendants are, respectively, jointly and severally liable to Plaintiff and the other Class Members for three times the damages Plaintiff and the other Class Members have sustained, plus the costs of bringing this suit,

including reasonable attorneys' fees.

217. By virtue of these violations of 18 U.S.C. § 1962(d), under the provisions of Section 1964(d) of RICO, Plaintiff and the other Class Members further seek injunctive relief against Defendants for their fraudulent reporting of list prices and kickback scheme, plus the costs of bringing this suit, including reasonable attorneys' fees. Absent an injunction, the effects of this fraudulent and unlawful conduct will continue. Plaintiff and the other Class Members will continue purchasing Manufacturer Defendants' at-issue drugs, and Plaintiff and the other Class Members will continue to pay based on Defendants' fraudulent list prices. In a country where tens of thousands of citizens cannot afford their medication needed to treat diabetes, or where the expense of such drugs is a great burden on millions, and there is no cure for diabetes, any continuing fraudulent and unlawful misconduct is a serious matter that calls for injunctive relief as a remedy.

COUNT THREE
VIOLATION OF THE ROBINSON-PATMAN ACT, 15 U.S.C. § 13(c)
(Against All Defendants on behalf of Plaintiff and the Class)

218. Plaintiff incorporates by reference the allegations contained in the preceding paragraphs.

219. Plaintiff asserts this claim against Defendants on behalf of themselves and the Class.

220. Section 2(c) of the Robinson-Patman Act provides:

> It shall be unlawful for any person engaged in commerce, in the course of such commerce, to pay or grant, or to receive or accept, anything of value as a commission, brokerage, or other compensation, or any allowance or discount in lieu thereof, except for services rendered in connection with the sale or purchase of goods, wares, or merchandise, either to the other party to such transaction or to an agent, representative, or other intermediary therein where such intermediary is acting in fact for or in behalf, of is subject to the direct or indirect control, of any party to such transaction other than the person by whom such compensation is so granted or paid.
> 15 U.S.C. § 13(c).

221. By engaging in the kickback and commercial bribery scheme described herein, Defendants have engaged in commercial bribery in violation of Section 2(c) of the Robinson-Patman Act, 15 U.S.C. § 13(c). Plaintiff acknowledges that this Court's July 2021 order in In re: Direct Purchaser Insulin Pricing Litigation dismissed without prejudice the Section 2(c) Robinson-Patman Act claims brought by Other Direct Purchaser Plaintiffs, See Case No. 3:20-cv-3426, ECF No. 158 at 15-16.

222. The PBM Defendants owed a legal duty to the Plaintiff and the other Class Members to negotiate rebates and fees and construct formularies for the benefit of the Plaintiff and other Class Members. The PBM Defendants have held themselves out as having superior knowledge and expertise about the pharmaceutical industry and the negotiation of prices and rebates with drug manufacturers. Because of their superior knowledge and expertise, Plaintiff and other Class Members retained the PBM Defendants to negotiate on their behalf for their benefit with Manufacturer Defendants with regard to formulary placement, price and rebates or fees in connection with the sale of drugs, including the at-issue drugs. Plaintiff and the Defendants all understood that the purpose of Plaintiff's retention of a PBM was to assist the Plaintiff to reduce the costs associated with providing prescription drugs to plan members.

223. Plaintiff trusted the PBM Defendants to make formulary placement decisions, including for the at-issue drugs, in Plaintiff's best interest and to help them manage and reduce the cost of acquiring drugs for their plan members. Plaintiff relied on the PBM Defendants to do so.

224. By accepting and retaining unearned rebates and fees from the Manufacturer Defendants or by having their respective Rebate Aggregator agents/designees accept and retain unearned and undisclosed rebates and "fees" on behalf of and for their benefit, the PBM

Defendants breached their duty to Plaintiff and the Class Members.

225. Zinc, Ascent and Emisar acted as the agents for and at the direction of their respective PBM Defendant in negotiating price, rebates and purported "fees" with the Manufacturer Defendants in connection with sale of the at-issue drugs to Class Members. The rebates and purported "fees" which Zinc, Ascent and Emisar received from the Manufacturer Defendants in connection with the sale of the at-issue drugs were received on behalf of and for the benefit of the respective PBM Defendants.

226. The Manufacturer Defendants also knew and understood that Zinc, Ascent, and Emisar were acting as the agents for and at the direction of their respective PBM's in negotiating price, rebates and purported "fees" for the acquisition of the at-issue drugs from the Manufacturer Defendants. The Manufacturer Defendants further knew and understood that the rebates and purported "fees" which they paid to Zinc, Ascent, and Emisar in connection with the sale of the at-issue drugs were being paid for the benefit and on behalf of the respective PBM Defendants and in exchange for favorable placement by the PBM Defendants of the Manufacturer Defendants' at-issue at-issue drugs on Plaintiff's and the other Class Members' formularies and that such placement was contrary to Plaintiff's and the other Class Members' interests.

227. If the Manufacturer Defendants had not paid the unearned and undisclosed rebates and purported "fees" to the PBM Defendants and their Rebate Aggregator agents/designees, the PBM's would not have granted the unwarranted and favorable formulary placement to the Manufacturer Defendants' at-issue drugs.

228. The Manufacturer Defendants artificially increased the price for the at-issue drugs by engaging in the kickback scheme described in this complaint.

229. The PBM Defendants sought, and the Manufacturer Defendants paid, kickbacks and

other unearned sums to the PBM Defendants, who are the agents and/or fiduciaries of for Plaintiff and the other Class Members, which were not disclosed to Plaintiff or Class Members.

230. When the kickbacks and other unearned sums were paid by the Manufacturer Defendants to the PBM Defendants, PBM Defendants were under the control of and/or working on behalf of Plaintiff and the other Class Members. The payments accordingly crossed the buyer/seller line.

231. The kickbacks and other unearned sums were paid to the PBM Defendants, who are the agents and/or fiduciaries for Plaintiff and similarly Class Members, without the consent of Plaintiff or members of the Class.

232. The kickbacks and other unearned sums were intended to influence the PBM Defendants to give the Manufacturer Defendants' at-issue drugs favorable placements on formularies and to continue participating in the illegal scheme to keep prices for the at-issue drugs artificially high.

233. Pursuant to the kickback scheme described above, Defendants created illegal inducements that resulted in artificially inflated prices.

234. As a result of Defendants' unlawful conduct, Plaintiff and the other Class Members purchased at-issue drugs at artificially inflated prices as a result of undisclosed and unearned fees and rebates.

235. There is no appropriate or legitimate business justification for Defendants' conduct. The payments to the PBMs were not for any services rendered.

236. Defendants' unlawful conduct has resulted in competitive injury to Plaintiff and the other Class Members by unduly restraining, hindering, suppressing, and/or eliminating competition in the sale of commodities in interstate commerce.

237. As a direct and proximate result of Defendants' unlawful actions detailed herein, Plaintiff and the other Class Members suffered substantial economic losses in the form of overcharges for the at-issue drugs.

238. Plaintiff and the other Class Members are entitled to recover treble damages and costs of suit, including reasonable attorneys' fees, pursuant to Section 4(a) of the Clayton Act, 15 U.S.C. § 15(a).

COUNT FOUR
VIOLATION OF THE MARYLAND CONSUMER PROTECTION ACT
MD. COM. LAW CODE § 13-101, ET SEQ.
(AGAINST ELI LILLY, NOVO NORDISK, AND SANOFI)

239. Plaintiff and all Maryland the other Class Members incorporate by reference the allegations contained in the preceding paragraphs.

240. The Maryland Consumer Protection Act ("Maryland CPA") provides that a person may not engage in any unfair or deceptive trade practice, including: "False, falsely disparaging, or misleading oral or written statement, visual description, or other representation of any kind which has the capacity, tendency, or effect of deceiving or misleading consumers"; "Failure to state a material fact if the failure deceives or tends to deceive"; "False or misleading representation[s] of fact which concern[] . . . [t]he reason for or the existence or amount of a price reduction"; and

241. "Deception, fraud, false pretense, false premise, misrepresentation, or knowing concealment, suppression, or omission of any material fact with the intent that a consumer rely on the same."

242. The statute further provides that a person may not engage in such conduct regardless of whether the consumer is actually deceived or damaged.

243. Defendants, Plaintiff and other Maryland the other Class Members are "persons" within the meaning of Md. Code, Com. Law § 13-101(h).

244. The Defendants' conduct, as described in this complaint, constitutes both "deceptive" and "unfair" acts or practices in violation of the Maryland CPA.

245. Pursuant to Md. Code, Com. Law § 13-408, Plaintiff and other Maryland the other Class Members seek actual damages, attorneys' fees, and any other just and proper relief available under the Maryland CPA. 120 Md. Code, Com. Law § 13-301. *Id.* § 13-302.

246. Plaintiff also seeks an order enjoining each defendant's unfair and/or deceptive acts or practices, punitive damages, and attorneys' fees, costs, and any other just and proper relief available under Md. Code, Com. Law § 13-406.

COUNT FIVE
CIVIL CONSPIRACY
(AGAINST ALL DEFENDANTS)

247. Plaintiff Baltimore City Schools and all Maryland the other Class Members incorporate by reference the allegations contained in the preceding paragraphs.

248. The Manufacturer and PBM Defendants confederated by mutual agreement or understanding to violate the Maryland Consumer Protection Act through their conduct as alleged above, causing financial losses to Plaintiff and all Maryland the other Class Members.

X. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiff, on behalf of themselves and the proposed Class, respectfully ask that this Court:

A. Determine that this action may be maintained as a Class action pursuant to Federal Rules of Civil Procedure 23(a), (b)(2) and (b)(3), and direct that reasonable notice of this action, as provided by Federal Rule of Civil Procedure 23(c)(2), be given to the Class, declare Plaintiff as the representative of the Class, and their counsel as Class Counsel.

B. Enter judgments against Defendants and in favor of Plaintiff and the Class;

C. Award Plaintiff and the Class damages (three times the overcharges) in an amount to

be determined at trial, or, in the alternative, treble the amount of the unearned and undisclosed rebates;

D. Award Plaintiff and the Class their costs of suit, including reasonable attorneys' fees and costs as provided by law;

E. Enjoin the Manufacturer Defendants from continuing to report artificially inflated list prices that do not approximate their true net prices to the PBM Defendants.

F. Award such further and additional relief as the case may require and the Court may deem just and proper under the circumstances.

XI. JURY DEMAND

On behalf of itself and the proposed Class, Plaintiff demands a trial by jury on all issues so triable.

Date: January 10, 2025

Respectfully submitted,

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